

Sr. No.	Application reference Number	Title of the clinical trial Protocol	Name of Sponsor	Principal Investigator (PI)	Clinical Trial Site	Trial Phase	Type of product (vaccine, drug, device)	Investigational Product (s)	# targeted trial participants	Trial duration	FDA Approval/Withdrawal/Rejection Date	Certificate Reference Number	Current regulatory Status	Date of Certificate Expiration	Current Implementation Status
1	<b>DIS/PSM/CT/201905020 01</b>	Pragmatic multicentre Factorial randomised controlled trial testing measures to reduce surgical site infection in low and middle income countries [FALCON]	University of Birmingham/ United Kingdom	NTIRENGANYA Faustin, MD, MMED,	CHUB, CHUK, KMH, Kibogora Hospital,	Phase IV	Medical Devices	2% alcoholic chlorhexidine solution/Triclosan-coated PDS or Vicryl sutures	2700	12 Months	23/05/2019	0579/Rwanda FDA/2019	Approved	22/05/2020	<b>Completed</b>
2	<b>DIS/PSM/CT/202004240 02</b>	A Phase 3 open-label randomized clinical trial to evaluate the safety, reactogenicity and immunogenicity of a 2-dose Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo in healthy pregnant women [INGABO]	Janssen Vaccines and Prevention B.V. (Janssen) Archimedesweg 4, 2333 CN Leiden, The Netherlands	Dr KARITA Etienne	GISENYI Hospital, GIHUNDWE Hospital	Phase III	Vaccine	Ebola vaccine regimen of Ad26.ZEBOV followed by MVA-BN-Filo	300	23 months	29/09/2020	003B/CT/RWANDA FDA/2020, 00R1/CT/RWANDA FDA/2022	Approved	27/08/2023	<b>Completed</b>
3	<b>DIS/PSM/CT/202004040 01</b>	Clinical validation of Novel Malaria Diagnostic Tools for point of care testing [NOVEL MALARIA]	FIND Project/ Geneva, Switzerland	Mr MUSABYIMANA, Jean Pierre, Dr NDISHIMYE	Hopital GITWE, HC RUHANGO and CHUB	Phase III	Medical Devices	Malaria P.f (HRP2/pLDH) Test	1470	11 months	23/06/2020	005/CT/RWANDA FDA/2021	Approved	6/22/2021	<b>Completed</b>

4	<b>DIS/PSM/C T/202011050 01</b>	ClustEr randomised Trial of sterile glove And instrument change at the time of wound closure to reduce surgical site infection [ <b>CHEETAH</b> ]	UNIVERSITY OF BIRMINGHAM Edgbaston, Birmingham, B15 2TT, UK	Dr JC Allen INGABIRE	CHUK, CHUB, RMH, KFH, Kibungo RH, Rwamagana PH, Bushenge PH, Ruhengeri RH, Kibuye RH, Butaro DHI, Kabgayi DH, Kibogora DH, Gahini DH, Ejo Heza clinic	Phase IV	Medical Devices	Gloves	1580	12 Months	9/7/2020	002R1/CT/FDA/2021	Approved	8/11/2022	<b>Completed</b>
5	<b>DIS/PSM/C T/202007270 01</b>	Clinical Study to Assess the treatment of Schizophrenia with Paliperidone Palmitate in Rwandan Helathcase settings [ <b>CASPAR</b> ]	Janssen-Cilag International N.V	Dr RUTAKAYIRE Bizoza, Dr Emmanuel Musoni Rwililiza and Dr Jean Nepo Utumatwishima	Neuropsychiatric Hospital CARAES Ndera, University Teaching Hospital of Kigali, Kibuye Referral Hospital, Rwamagana Provincial Hospital	Phase IV	Drugs	Paliperidone Palmitate 3PPM, 1PPM	100	71 Weeks	23/06/2021	011C/CT/RW/ANDAF/DA/2021	Approved	12/16/2023	<b>Completed</b>

6	<b>DIS/PSM/C T/201909260 01</b>	INVESTIGATION of rheumatoid Arthritis Treatment Using vitamin K antagonists, rivaroxaban or aspirin Studies [INVICTUS]	Population Health Research Institute Hamilton Health Sciences and McMaster University, Hamilton, Canada	Dr Emmanuel RUSINGIZA	CHUK	Phase IV	Drugs	Vitamin K	32	60 Months	12/03/20 22	029/RN EC/ 2021, 96/RNE C/2 022	Approved	03/11/20 23	<b>Completed</b>
7	<b>DIS/PSM/C T/202000909 001</b>	High-dose intravenous vitamin C as an adjunctive treatment for sepsis in Rwanda: A feasibility trial. [VITAMIN C]	Virginia Commonwealth University	Dr Dennis Hopiknson	CHUK	Phase II	Drugs	Ascor® (Ascorbic Acid Injection, USP)	24	12 months	6/1/2021	009/CT/ RWA NDAFD A/202 1	Approved	5/31/202 2	<b>Stopped by Sponsor</b>
8	<b>DIS/PSM/C T/202010050 01</b>	Preventing Pulmonary Complications in Surgical Patients at Risk of COVID 19 [PROTECT-Surg]	University of Birmingham	Prof NTIRENGANY A Faustin	CHUK, CHUB, Ruhengeri RH, Kibungo RH, Kibogora DH &Kibagabaga DH	Phase III	Drugs	RESP301	300	12 Months	31/12/20 20	003A/C T/RW ANDA FDA/202 0	Approved	2/1/2024	<b>Suspended by Sponsor</b>
9	<b>DIS/PSM/C T/202011160 01</b>	Safety and Pharmacokinetics of the Combination Broadly Neutralizing Antibodies, 3BNC117-LS-J and 10- 1074-LS-J, in Healthy American and African Adults [ANTIBODIES]	International AIDS Vaccine Initiative (IAVI), 125 Broad Street, 9th Floor New York 10004, USA	Dr KARITA Etienne	Center for Family Health Research (CFHR)	Phase I/II	Vaccine	Neutralizing Antibodies, 3BNC117- LS-J and 10-1074-LS- J	176	92 weeks	18/06/20 21	006/CT/ RWA NDA FDA/202 1	Approved	3/14/202 4	<b>Completed</b>
10	<b>DIS/PSM/C T/202011260 02</b>	Wondfo Malaria P.f (HRP2/pLDH) Test [WONDFO]	Gangzhou Wondfo Biotech Co., Ltd, China	Dr Pacifique NDISHIMYE	Remera, Nyarugunga and Busanza Health Centers	NA	Medical Devices	Malaria Tests	1470		19/02/20 21	005/CT/ RWA NDA FDA/202 1	Approved	18/02/20 22	<b>Completed</b>

11	<b>DIS/PSM/C T/202012210 02</b>	A Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Prothione™ Capsules for Mild to Moderate Coronavirus Disease 2019 (COVID-19). [PROTHIONE]	Three Aminos, LLC P.O. Box 3026 Alpharetta, GA 30023 USA	Dr. Vincent Mutabazi	Rinda Ubuzima, University of Rwanda, Campus Remera, P.O. Box 4560 Kigali, Rwanda	Phase II	Drugs	Prothione™ Capsules	200	44 Weeks	18/03/20 21	007A/C T/RW ANDA FDA/202 1	Approved	10/22/20 22	<b>Completed</b>
12	<b>DIS/PSM/C T/202012110 01</b>	A randomized, parallel-group, placebo-controlled, double-blind Phase 1/2a study in healthy HIV- uninfected adults to assess safety/ tolerability and immunogenicity of 2 different prime/ boost regimens: priming with tetravalent Ad26.Mos4.HIV and boosting with tetravalent Ad26.Mos4.HIV and either Clade C gp140 plus adjuvant OR a combination of Mosaic and Clade C gp140 plus adjuvant. [HPX2003]	Janssen Vaccines & Prevention B.V.	Dr Etienne Karita	Projet San Francisco	I/II	Vaccine	Ad26.Mos4.HI V tetravalent vaccine, IM; Clade C gp140 monovalent vaccine, IM; Mosaic gp140 monovalent vaccine, IM	150	78 weeks	14/04/20 21	001/CT A/RW ANDA FDA/202 1, 001R1/C TA/ RWAND A FDA/202 2,	Approved	10/4/202 3	<b>Completed</b>
13	<b>DIS/PSM/C T/202101150 01</b>	Study of TriAntiMal™ in the treatment of Malaria in Rwanda [TriAntiMal™]	Dr. Jerry T. Thornthwaite, Director of Cancer Research Institute of West Tennessee, USA	Dr. William Rutagengwa	Nyamata District Hospital, Nyamata Health Center	Phase III	Drugs	TriAntiMal™	50	4 months	8/6/2021	007/CT/ RWA NDA FDA/202 1	Approved	7/6/2022	<b>Completed</b>
14	<b>DIS/PSM/C T/202101150 01</b>	Evaluation of the efficacy of artemether-lumefantrine and dihydroartemisinin-piperaquine in children with uncomplicated clinical malaria in Rwanda- [TES]	PMI/Impact Malaria/ USAID	Dr Aline Uwimana, & Dr Noella Umulisa,	Rukara Health Center, Masaka Health Center	Phase IV	Drugs	Artemether- lumefantrine and dihydroartemisi nin- piperaquine tablet	528	18 months	1/6/2021	008/CT/ RWA NDA FDA/202 1	Approved	11/8/202 3	<b>Close-out phase</b>

15	<b>DIS/PSM/CT/202011250 02</b>	An adaptive, randomized, active-controlled, open-label, sequential cohort, multicentre study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of intravenous cipargamin (KAE609) in adult and paediatric participants with severe Plasmodium falciparum malaria [KARISMA]	NOVARTIS	Dr Aline Uwimana Dr Sumanyi Jean Claude Marie Michelle Umurisa	Rwanda Military Hospital	Phase II	Drugs	Cipargamin (KAE609) IV injection, 10 mg/ml and/ or 15mg/ml vial	100	36 months	29/10/2021	012/CT AC/F DA/2021	Approved	28/10/2022	<b>Close-out phase</b>
16	<b>DIS/PSM/CT/20210317</b>	Anti-Coronavirus Therapies (ACT) to prevent progression of COVID-19: Randomized trials [COLCHICINE]	Hamilton Health Sciences, through its Population Health Research Institute David Braley Cardiac, Vascular and Stroke Research Institute Hamilton General Hospital, CANADA	Dr.Nkeshimana Menelas	CHUK	Phase III	Drugs	Aspirin cardio, Xarelto 2.5 mg film-coated tablets and Colchicine 0.5mg tablets	250	6 months	12/8/2021	013/CT AC/F DA/2021	Approved	12/1/8/2022	<b>Stopped by Sponsor</b>
17	<b>DIS/PSM/CT/20211001</b>	A Global, Multi-center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01) in Adults Aged 18 Years and Older study	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, China	Dr. Utumatwishima Jean Nepo Abdallah	Rwamagana Provincial Hospital	Phase III	Vaccine	Influenza Virus Vector COVID-19 Vaccine for Intranasal Spray (DelNS1-2019-nCoV- RBD-OPT1	32,000	20 months	30/12/2021	NA	Withdrawn	NA	<b>Withdrawn</b>

18	<b>DIS/PSM/CT/202110310 01</b>	“A multi-centre randomized controlled non-inferiority trial to compare the efficacy, safety and tolerability of Triple Artemisinin- based Combination Therapies versus first-line ACTs + placebo for the treatment of uncomplicated Plasmodium falciparum malaria in Africa” [ <b>DETECT</b> ]	University of Oxford.	Prof Leon Mutesa, MD, PhD	UR	Phase III	Drugs	Artemether-Lumefantrine and Amodiaquine and /Artemether –Lumefantrine and Placebo	216	20 months	2/8/2022	014/CT AC/F DA/2022	Approved	1/8/2023	<b>Completed</b>
19	<b>DIS/PVSM/CT/2021090 7001</b>	Phase 2/3 Randomized, Blinded, Placebo-Controlled Trial to Evaluate the Safety, Immunogenicity, and Efficacy of INO-4800, a Prophylactic Vaccine against COVID-19 Disease, Administered Intradermally Followed by Electroporation in Adults at High Risk of SARS-CoV-2 Exposure [ <b>INNOVATE</b> ]	Inovio harmaceuticals, Inc.660 W. Germantown Pike, Suite 110 Plymouth Meeting, PA 19462	Dr MUTABAZI Vincent & Dr. Karita Etienne	RINDA UBUZIMA, CFHR	Phase III	Vaccine	INO-4800 COVID 19 Vaccine	7116	3 years	05/4/2022	NA	Withdrawn	NA	<b>Withdrawn</b>
20	<b>DIS/PSM/CT/20221401</b>	Safety and efficacy of cassava leaf extract lozenges to reduce the SARS-CoV-2 viral load in the oral (and nasal) cavities of mild/ asymptomatic Covid-19 positive individuals. A Proof-of-Concept Study in Rwanda [ <b>CASSAVA LEAF</b> ]	Mycobriah Ltd, USA	Dr. Menelas NKESHIMAN A Centre, CHUK	CHUK, CHUB, GISENYI DH	NA	Other	CASSAVA LEAF	49	12 months	21/4/2022	015/CT AC/F DA/2022	Approved	20/4/2023	<b>Completed</b>

21	<b>DIS/PSM/C T/202203070 01</b>	A Multi-Centre, Randomized, Double Blind, Phase 2b Trial to Evaluate the Safety and Immunogenicity of Janssen Ad26COVS1 and Novavax NVX-CoV2373 COVID-19 vaccines for Homologous and Heterologous Boosting in Adolescents and Adults Aged 12 to 64 Years with and without HIV infection in 3 African Countries (Kenya, Democratic Republic of Congo, and Rwanda [VIBRI])	Victoria Biomedical Research Institute, Kenya	Dr. Vincent Mutabazi, MD, MSc.	SAKE /RUKOMO Health Center, Ngoma District and Rinda Ubuzima Head Quarter, Gasabo District.	Phase III	Vaccine	Novavax NVX-CoV2373 vaccine and Janssen Ad26COVS1 vaccine	1950	30 Months	01/6/2022	016/CT AC/F DA/2022	Approved	31/05/2023	<b>Completed</b>
22	<b>DISP/SM/C T/20221401</b>	Effect of Honey versus conventional dressing in the Management of open fractures wounds [The HORSE Trial].	Dr. Jean de la Croix ALLEN INGABIRE, Student at Texila American University	Dr. Jean de la Croix ALLEN INGABIRE.	Centre Hospitalier Universitaire de Kigali (CHUK), Nyarugenge District	NA	Other	Buranga Natural Honey	98	24 months	17/6/2022	017/CT AC/F DA/2022	Approved	16/6/2023	<b>Completed</b>
23	<b>DIS/PSM/C T/202108200 01</b>	A Phase 1 Study to Evaluate the Safety and Immunogenicity of eOD- GT8 60mer mRNA Vaccine (mRNA- 1644) in HIV-1 Uninfected Adults in Good General Health [IAVI G003]	International AIDS Vaccine Initiative (IAVI). 125 Broad Street, 9th Floor, New York 10004 USA	Dr. Julien NYOMBAYIRE	Center for Family Health Research, Rwanda	Phase I	Vaccine	eOD-GT8 60mer mRNA Vaccine (mRNA-1644),0.6mL /2-mL glass vials	18	12 months	17/6/2022	018/CT AC/F DA/2022	Approved	16/6/2023	<b>Completed</b>
24	<b>CTA-6411- 2022</b>	VAC31518COV2004 An Open-label, Phase 2 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26.COVS1 in Healthy Pregnant Participants [ HORIZON 1]	Janssen Vaccines & Prevention B.V. Archimedesweg 4 Leiden 2333 CN, Netherlands	Dr Etienne Karita	Center for Family Health Research, Rwanda	Phase II	Vaccine	Ad26.COVS1 (also known as Ad26COVS1), Monovalent vaccine	400	21 months	05/8/2022	NA	Withdrawn	NA	<b>Withdrawn</b>

25	<b>DIS/PSM/C T/202012110 01</b>	Contrast-Enhanced Ultrasound in the Evaluation of Abdominal Solid Organ Injuries in Trauma Patients <b>[LUMASON ]</b>	David P. Mooney, MD, MPH 300 Longwood Avenue Boston, USA	Dr. Vincent Ndebwanimana	CHUK	Phase I/II	Medical Devices	Sulfur hexafluoride lipid type A microspheres, injectable suspension, 25 mg of lipid-type A lyophilized powder	22	10 months	17/7/2022	NA	Withdrawn	NA	<b>Withdrawn</b>
26	<b>DIS/PSM/C T/202106110 01</b>	The impact of selenium Supplementation in the treatment of COVID 19 positive patients in Rwanda <b>[SELENIUM]</b>	NCST Rwanda & Selenium Education and Research Center SA	Dr. Kamwesiga Julius	King Faysal Hospital	Phase III	Drugs	Selenium supplement tablets	100	38 weeks	28/9/2022	019/CT AC/F DA/2022	Approved	27/9/2023	<b>Stopped by Sponsor</b>
27	<b>DIS/PSM/C T/202206002 001</b>	<b>[SPIKER/RW/CT/CTG-AI Version 02]</b> A Clinical Investigation Evaluating Efficacy of an Intelligent Cardiotocography with Real-Time Alerts for an Improved Labor and delivery	Spiker Ltd. 2-5 Inage-ku, Chiba, Japan	Dr. Kizito Nkurikiyeyezu, Dr. Vincent Dusingizimana	Hopital La Croix du Sud	NA	Software/ Medical Devices	SPIKER AI-CTG (EDAN CTG F9)	200	12 months	11/10/2022	020/CT AC/F DA/2022	Approved	10/10/2023	<b>Suspended by Authority</b>

28	<b>DIS/PVSM/CT/CTA- 16499-2022</b>	A phase I/II partially randomized, active-controlled (BNT162b2/COMIRNATY®), observer-blind, dose selection, safety, and immunogenicity study of GLB-COV2-043, an mRNA vaccine candidate against SARS-CoV-2, administered as a single-vaccination booster to previously vaccinated adults. [GLB-003]	GreenLight Biosciences, Inc E-mail address: akhan@greenlightbio.com Phone number (with country code): +1(202) 997-1231	Dr Etienne Karita, Prof. Leon Mutesa Eric Remera Augustin Murindabigwi Igiraneza Deborah Sibomana Hassan	Rwanda Teaching Hospital in Butare, Southern Province. The Center for Family Health Research in Kigali.	Phase I/II	Vaccine	GLB-COV2-043 DS , IM 0.5mL per vial); 0.48mg/mL (Test product) & BNT162b2 (COMIRNATY®), mRNA vaccine against the spike (S) protein of SARS-CoV-2, by Pfizer/ BioNTech (Comparator)	48	24 months	26/1/2023	021/CT AC/F DA/2023	Approved	25/1/2024	<b>Stopped by Sponsor</b>
29	<b>DIS/PVSM/CT/CTA- 15192-2023</b>	All-oral shorter treatment regimen for multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB): Evaluating its effectiveness, safety and impact on the quality of life of patients in Rwanda” [STAKE]	Rwanda Biomedical Centre & Institute of Tropical Medicines/Belgium	Yves Habimana-Mucyo, Dr Patrick MIGAMBI Jean Claude SEMUTO NGABONZIZA ,Augustin DUSHIME	Two MDR-TB treatment centers, one within Kigali (Kibagabaga hospital) and another in the southern porovince (Kabutare hospital)	Phase II	Drugs	Amikacin 500 mg/2ml solution for injection	20	21 months	08/2/2023	022/CT AC/F DA/2023	Approved	07/2/2024	<b>Completed</b>

30	<b>DIS/PVSM/CT/CTA- 17687-2022</b>	Clinical Validation of Novel Malaria Diagnostic Tools for point-of-Care Testing, Innovation Platform Round 2	FIND, the global alliance for diagnostics	Jean Pierre Musabyimana	Byimana HC &Rwaniro HC, catchment area of CHUB	Phase III	Medical Devices	Index tests: Truenat® Malaria Pv/Pf test, Truenat® Malaria Pv/Pf Hi-Sens, Humasis has-Malaria p.f./Pan Test, Optical imaging of hemozoin	509	11 months	15/2/2023	023/CT AC/F DA/2023	Approved	14/2/2024	<b>Completed</b>
31	<b>DIS/PVSM/CT/CTA- 17687-2022</b>	Testing the reliability of the novel IMPALA patient care monitoring system for critically ill infants and children [IMPALA-REL]	GOAL 3 Rwanda Ltd	Dr. Janvier Hitayezu	University Teaching Hospital of Kigali (CHUK). Rwanda	NA	Medical Devices	IMPALA patient care monitoring systems	15	6 months	27/4/2023	024/CT AC/19 71-2023/FDA/18 69/2023	Approved	26/10/2024	<b>Stopped by Sponsor</b>
32	<b>DIS/PVSM/CT/CTA- 7482-2022</b>	Status of blood Blood Pressure and Cardiovascular Risk Control assessment among hypertensive patient attending Nyamyumba Health Center in a rural District of Nyaruguru.	BIANCHETTI Mario, Prof.Dr.med, MD Stiftung für Herz- und Gefäßkrankheiten	Dr. Bienvenu Muvunyi	Health Centre Nyamyumba, Sector Mata, District Nyaruguru	Phase IV	Drugs	20mg Olmesartanum medoxomilum / 5mg Amlodipinum/ 12.5mg Hydrochlorothiazidum 40mg Olmesartanum medoxomilum / 10mg Amlodipinum/ 12.5mg Hydrochlorothiazidum	384	12 months	06/11/2023	025/CT A/748 2-2023 /FDA/46 70 /2023	Approved	05/11/2024	<b>Ongoing Implementation</b>

33	<b>DIS/PVSM/ CT/CTA- 6938- 2023</b>	A Phase I/IIa (Multicenter, Open Label, Dose Escalation, Phase I/Multicenter, Observer -Blinded, Randomized, Placebo-Controlled, Phase IIa) Trial to Evaluate the Safety, Tolerability and Immunogenicity of the STP2250 mRNA-Based COVID-19 Vaccine Administered as a Booster to Healthy Adults Aged 19-55 Years Old	ST Pharm Co., Ltd. 520 Yeongdong- daero, Gangnam- gu, Seoul 06170, Republic of Korea	Prof. Leon MUTESA & Prof.Dong – Gun Lee	Centre Hospitalier Universitaire de Butare (CHUB), Rwanda	Phase I/II	Vaccine	STP2250 IM Injection solution 0.05 g/L for 25 µg/human or 0.1 g/L for 50 µg/human (Dose escalation).	120	18 months	23/11/2023	028/CT AC/16 938-2023/FDA/52 60/2023	Approved	22/11/2024	<b>Stopped by Sponsor</b>
34	<b>RWANDA- FDA23/CTR /0005</b>	Building Respiratory support in East Africa Through High flow versus standard flow oxygen Evaluation.[ <b>BREATHE</b> ]	Beth Israel Deaconess Medical Center (BIDMC) 330 Brookline Avenue Boston, MA, USA 02215	Jeanine Condo MD,PhD and Elisabeth Riviello, MD, MPH	Centre Hospitalier Universitaire de Kigali(CHUK) and Centre Hospitalier Universitaire de Butare (CHUB). Rwanda	NA	Medical Devices	High Flow Oxygen (HFO) using Airvo2 device for oxygen delivery	420	15 months	06/11/2023	026/CT A/000 5/FDA/4 672 /2023	Approved	05/11/2024	<b>Ongoing Implementat ion</b>

35	<b>RWANDA-FDA24/CTR/0005</b>	A multi-part, multi-center PLATform study to assess the efficacy, safety, tolerability and pharmacokinetics of anti-malarial agents administered as monotherapy and/or combination therapy IN patients with Uncomplicated Plasmodium falciparum Malaria[ <b>PLATINUM</b> ]	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel, Switzerland	Dr. Aline UWIMANA	Rinda Ubuzima-Rwanda Military Hospital Rue 47 Remera, Gasabo District, 4560, Kigali, Rwanda	Phase II	Drugs	KLU 156(400mg KAF156,480mg LUM SDF) Once ; Cipargamin (KAE609 25 mg) 75mg Once;Artemether- 480 mg Lumefantrine ) Twice daily	60	24 months	20/2/2024	029/CT A/ 7789-2023/FDA/08 14/2024	Approved	19/2/2025	<b>Initiation Phase</b>
36	<b>RWANDA-FDA23/CTR/0006</b>	A Phase 2a, Multicenter, Open-label, Dose-finding, Dose escalation Study of Meplazumab in Adult Patients diagnosed with Uncomplicated Plasmodium falciparum Malaria.Protocol Number and version: MPZ- MAL-01[Amendment 1] dated 27 July 2023	Jiangsu Pacific Meinuoke Biopharmaceutical Co., Ltd. No.128 Hehai West Rd, Xinbei District, Changzhou 213022, Jiangsu, China.	Dr. Mossi NZEYIMA NA;Dr.Muco MUGISHA Mc Juan; Dr.Julien NYOMBA YIRE	Rinda Ubuzima-Rwanda Military Hospital, Gasabo District; Gatenga Health Center-Rinda Ubuzima,Kicukiro District; Center for Family Health Research-Gisenyi District Hospital, Rubavu District	Phase 2a	Biologic	Meplazumab for Injection Ketantin® a humanized IgG2 monoclonal antibody specific to CD147 receptor	60	182 days	03/04/2024	030/CT A/0006 /FDA/ 645 /2024	Approval	02/04/2025	<b>Close-out phase</b>

37	<b>RWANDA-FDA24/CTR/0003</b>	Faster elimination of HPV infection and cervical cancer using concomitant HPV vaccination and HPV screening: A demonstration project in Rwanda. Protocol Number and version: Version 01, dated 23 May 2024	Merck 126 East Lincoln Avenue, P.O Box 2000 Rahway, NJ 07065 USA	Dr.Francois UWINKIN DI	Rwanda Biomedical Centre, Kigali- Rwanda.	Phase IV	Vaccine	Gardasil 9® (recombinant DNA HPV vaccine) suspension of 0,5ml, IM Injection	110,636	30 months	03/06/2024	031/CTA/0003/FDA/2479/2024	Approved	01/06/2026	<b>Ongoing Implementation</b>
38	<b>RWANDA-FDA24/CTR/0004</b>	Fetal Biometrics Ultrasound Screening assisted by Artificial Intelligence (BabyBuddy).Protocol Number and version: Version 01, dated 10 July 2024	IRCAD-Africa, 2 KN 30 St, Kigali-Rwanda, 6th Floor Alliance Tower (PCD)	Dr. King R KAYONDO.	University Teaching Hospital of Kigali (CHUK), 1024, rue de la Paix, P.O. Box 655;Nyarugenge, Kigali City.	NA	Software/ Medical Device	•BabyBuddy: AI drive US Fetal examination system	600	12 months	23/07/2024	032/CTA/0004/FDA/3295/2024	Approved	22/07/2025	<b>Ongoing Implementation</b>
39	<b>RWANDA-FDA24/CTR/0009</b>	A Phase 2 Rapid Response, Open-Label Study to Assess Safety and Immunogenicity of an Investigational Monovalent Chimpanzee Adenoviral-Vectored Marburg Virus Vaccine in Adults in an Outbreak Setting.	Rwanda Biomedical Centre, Kigali-Rwanda	Dr.Hassan SBOMANA	Centre Hospitalier Universitaire de Kigali(CHUK), King Faisal Hospital (KFH) & Rwanda Military Hospital (RMH).	Phase II	Vaccine	cAd3-Marburg vaccine suspension of 1.0 × 10 <sup>11</sup> PU single dose, IM Injection	700	118 Days	03/10/2024	033/CTA/0009/FDA/4413/2024	Approved	02/10/2025	<b>Completed</b>

40	<b>RWANDA-FDA24/CTR/0016</b>	A Two Part Phase 2, Rapid Response, Open-Label, Randomized Study to Safety, Efficacy and Immunogenicity of an Investigational Monovalent Chimpanzee Adenoviral-Vectored Marburg Virus Vaccine in Adults in an Outbreak Setting	Rwanda Biomedical Centre, Kigali-Rwanda	Dr.Hassan SBOMANA	Centre Hospitalier Universitaire de Kigali(CHUK), King Faisal Hospital (KFH) & Rwanda Military Hospital (RMH)	Phase II	Vaccine	cAd3-Marburg vaccine suspension of $1.0 \times 10^{11}$ PU single dose, IM Injection	1600	118 days	28/10/2024	RWA-FDA/DD-CTA/10-2024/0016/036/4961	Approved	27/10/2025	<b>Completed</b>
41	<b>RWANDA-FDA24/CTR/0010</b>	Platform Adaptive Randomised Trial for NEw and Repurposed Filovirus treatments	World Health Organization [WHO]	Dr. Turatsinze David	Baho International Hospital_ Marburg treatment Centre,Kigali-Rwanda	Phase II/Phase III	Drugs and Biologics	<ul style="list-style-type: none"> <li>• Remdesivir: Adult &amp; Paediatric dose schedule IV Infusion</li> <li>• MBP091: Single dose IV Infusion</li> </ul>	To be adjusted over time	56 Days	12/10/2024	RWA-FDA/DD-CTA/10-2024/0010/034/4556	Approved	11/10/2025	<b>Completed</b>
42	<b>RWANDA-FDA24/CTR/0008</b>	A randomized, double-blinded, placebo-controlled, multicenter trial of azithromycin prophylaxis for advanced HIV disease: Reducing mortality in adults with advanced HIV disease. (REVIVE)	Population Health Research Institute,237 Barton Street East, Hamilton, Ontario L8L 2X2 Canada	Dr. Leopold BITUNGUHARI	Centre Hospitalier Universitaire de Kigali (CHUK), Nyarugenge District, Kigali_ Rwanda	Phase III	Drugs	Azithromycin oral tablet 250mg OD for 28 days	8000	12 months	16/12/2024	RWA-FDA/DD-CTA/09-2024/0008/038/6142	Approved	15/12/2025	<b>Ongoing Implementation</b>

43	<b>RWANDA-FDA24/CTR/0006</b>	Perioperative respiratory care and outcomes for patients Undergoing high risk abdominal surgery (PENGUIN)	Dr Birgit Whitman University of Birmingham Research Governance Team University of Birmingham Birmingham, B15 2TT researchgovernance@contacts.bham.ac.uk	Prof Faustin NTIRENGANYA University of Rwanda E-mail address: fostino21@yahoo.fr	University Teaching Hospital of Kigali(CHUK), University Teaching Hospital of Butare (CHUB) Kibagabaga Level II Teaching Hospital, King Faisal Hospital(KFH) Kibogora Level II Teaching Hospital	Phase IV	Drugs	. Preoperative chlorhexidine mouthwash and 80-100% FiO2 during surgery .Preoperative chlorhexidine mouthwash and 21-35% FiO2 during surgery	500	24 Months	31/12/2024	RWA- FDA/DD- CTA/05- 2024/00 06/039/6 498	Approved	29/12/2026	<b>Ongoing Implementation</b>
44	<b>RWANDA-FDA24/CTR/0010</b>	A Phase 2, Single-Arm Study of Obeldesivir for Postexposure Prophylaxis of Marburg Virus Disease	Gilead Sciences, Inc.333 Lakeside Drive Foster City, CA 94404 USA Rob Hyland	Dr. Menelas NKENSHIMA NA	King Faisal Hospital Rwanda KG 544 Street 10, Kacyiru, Gasabo, Kigali_ Rwanda	Phase II	Drugs	Obeldesivir Oral tablet BID for 10 days	400	12 Months	07/11/2024	RWA- FDA/DD- CTA/10- 2024/00 10/037/5 175	Approved	06/11/2025	<b>Stopped by Sponsor</b>

45	<b>RWANDA-FDA24/CTR/0009</b>	A Phase 4, Multicentre non-inferiority cluster randomised trial testing Disposable versus Reusable drApes and Gowns for green OperatiNg theatres.	Birmingham Clinical Trials Unit (BCTU), Institute of Applied Health Research, College of Medical and Dental Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT	Dr. Allen INGABIRE JC	Kigali University Teaching Hospital (CHUK),King Faisal Hospital (KFH)  Kibagabaga Level II Teaching Hospital,Rwamagana Level II Teaching Hospital,Kibungo Level II Teaching Hospital, Ruhengeri Level II	Phase IV	Medical D	<ul style="list-style-type: none"> <li>• Disposable (Single- use) drapes and gowns</li> <li>• Reusable drapes and gowns</li> </ul>	2600	12 Month	31/12/2024	RWA-FDA/DD-CTA/09-2024/009/040/6499	Approved	29/12/2026	<b>Ongoing Implementation</b>
46	<b>RWANDA-FDA24/CTR/0005</b>	A randomized, open-label, multicenter study to compare efficacy, safety and tolerability of KLU156 with Coartem® in the treatment of uncomplicated Plasmodium falciparum malaria in adults and children ≥ 5 kg body weight followed by an Extension phase with repeated KLU156 treatment.	Novartis, South Africa (Pty) Ltd Magwa Crescent West, waterfall City, Gauteng, 2090,South Africa.	Dr Mossi Nzeyimana	Rinda Ubuzima-Rwanda Military Hospital, CFHR Gisenyi Hospital, CFHR Gihundwe Hospital, Rwesero Health Center and Gatenga Health Center	Phase III	Drugs	KLU156A1 (ganaplacide/lu mefantrine-Solid Dispension Formulation)	400	43 days (Core phase, plus 24 months (Extension phase)	18/10/2024	RWA-FDA/DD-CTA/10-2024/005/035/4679	Approved	18/10/2025	<b>Close-out phase</b>

47	<b>RWANDA-FDA25/CTR/0002</b>	Phase 2a, open-label, randomized, interventional study to assess the safety and immunogenicity of alternative vaccination regimens and reduced antigen doses of RTS,S/AS01E vaccine in healthy children aged 5-60 months in a malaria-endemic area.	Ashwani Kumar Arora, GSK Vaccines Institute for Global Health (GVGH), ashwani.k.arora@gsk.com , 3934699887366	Dr Julien Mutagisha Nyombayire & Dr. Mossi Nzeyimana	Center for Family Health Research (CFHR), KK 19Ave57 Kicukiro, Kigali, Rwanda and Rinda Ubuzima/ Gatenga Medicalized Health Center	Phase 2a	Vaccine	Malaria vaccine (RTS,S/AS01E)	238	19 months	30/06/2025	RWA-FDA/DD-CTA/02-2025/0002/049/2192	Approved	29/06/2026	<b>Ongoing Implementation</b>
48	<b>RWANDA-FDA24/CTR/0011</b>	Efficacy of Human Papillomavirus (HPV) Vaccination to Prevent Infection Among Women Living with HIV: A Prospective, Individual, Double-Blind, Randomized Controlled Study.	Massachusetts General Hospital, email: mgsubs@mgb.org 55 Fruit Street, Boston, 02114	Dr. Fredrick Kateera. Partners in Health fkkateera@yahoo.com, +250784684871	Center for Family Health Research (CFHR)	Phase IV	Vaccine	Nonavalent HPV vaccine (GARDASIL@9)	200	30 months	17/06/2025	RWA-FDA/DD-CTA/12-2024/0011/048/2045	Approved	16/06/2026	<b>Ongoing Implementation</b>
49	<b>RWANDA-FDA24CTR0013</b>	EbolaCov: A phase IV, single-centre, single-blinded, randomized controlled trial to assess safety and immunogenicity of rVSVΔG-ZEBOV-GP vaccination when dosed concurrent with mRNA COVID-19 vaccine booster doses in healthy African adults.	University of Birmingham	Dr Julien Mutagisha Nyombayire	Center for Family Health Research (CFHR) KK 19Ave57 Kicukiro, Kigali, Rwanda	Phase IV	Vaccine	- Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live), - Comirnaty - COVID-19 mRNA Vaccine	72	180 days	20/05/2025	RWA-FDA/DD-CTA/12-2024/0013/047/1679	Approved	19/05/2026	<b>Initiation Phase</b>
50	<b>RWANDA-FDA25/CTR/0003</b>	An open-label, randomised, controlled, non-inferiority trial to compare the efficacy,safety and tolerability of a fixed dose Triple Artemisinin-based Combination Therapy (TACT) artemether-lumefantrine-amodiaquine versus first-line Artemisinin-based Combination Therapies (ACTs) for the treatment of uncomplicated Plasmodium	University of Oxford Research Governance, Ethics and Assurance, Boundary Brook House, Churchill Drive, Oxford OX3 7GB United Kingdom	Professor Leon Mutesa, University of Rwanda, lmutesa@gmail.com, +250-788451013	Ruhuha Health Centre-Nyamata District Hospital-Bugesera District	Phase III	Drugs	Artemether-Lumefantrine-Amodiaquine; Artemether-Lumefantrine; Artesunate-Amodiaquine	204	14 Months	11/7/2025	RWA-FDA/DD-CTA/04-2025/0003/050/2313	Approved	10/7/2026	<b>Ongoing Implementation</b>

51	<b>RWANDA-FDA25/CTR/0011</b>	Bag CPAP versus Standard Oxygen Care for the Management of Acute Hypoxemic Respiratory Failure in Adults: A Randomized Controlled Trial	University of Rwanda (UR), Rwanda Ministry of Health (MoH), Greater Paris University Hospitals (AP-HP) and University of Paris-Est Creteil (UPEC)	Dr. MUTEMBE Nzobebe Bruce	Kigali University Teaching Hospital (CHUK), RMR Teaching Hospital, Ruhengeri I2 Teaching Hospital	Phase IV	Medical Devices	Bag CPAP non-invasive ventilation device	250	10 months	14/7/2025	RWA-FDA/DD-CTA/05-2025/003/051/2334	Approved	13/7/2026	<b>Initiation Phase</b>
52	<b>RWANDA-FDA25/CTR/0010</b>	A stratified Multi-Arm, multi-site Randomised platform trial aiming to reduce the Incidence of post-operative SSP – MARLIN	University of Birmingham, t.pinkney@bham.ac.uk	Prof. Faustin Ntirenganya	University teaching of Kigali (CHUK), University teaching of Butare (CHUB), King Faysal Hospital (KFH),	Phase IV	Drugs and Medical devices	Chlorhexidine Gluconate pre-operative shower, Granudacyn Topical wound wash,Leukomed Sorbact DACC	2000	24 Months	26/9/2025	RWA-FDA/DD-CTA/05-2025/0010/052/3563	Approved	25/09/2026	<b>Ongoing Implementation</b>
53	<b>RWANDA-FDA25/CTR/0004</b>	Evaluation of the mHealth-Community Health Worker tool for comprehensive post-cesarean follow-up in rural Rwanda	National Institutes of Health,Phone number : +1 301-496-4000	Dr. Frederick Kateera , Dr. Bethany Hedt-Gauthier	Kirehe District Hospital	Pilot stage	mHealth technology/Software Medical Device (SaMD)	Mobile Health-Community Health Worker (mHealth-CHW) tool	1350	9 Months	17/10/2025	RWA-FDA/DD-CTA/04-2025/004/053/3860	Approved	16/10/2026	<b>Initiation Phase</b>

**Prof.Emile BIENVENU**  
**Director General**