RWANDA FDA
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RWANDA FDA CLINICAL TRIAL REGISTER, UPDATE OF DECEMBER 2023

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	**DIS/PSM/CT/20190502001**	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**	**2,700**	**12 Months**	**23/05/2019**	**0579/Rwanda FDA/2019**	**Approved**	**22/05/2020**	**Completed**
2	**DIS/PSM/CT/20200424002**	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**	**8/27/2023**	**Closed out phase**
3	**DIS/PSM/CT/20200404001**	Clinical validation of Novel Malaria Diagnostic Tools s for point of care testing **[NOVEL MALARIA]**	FIND Project/ Geneva, Switzerland	Mr MUSABYIMANA, Jean Pierre, Dr NDISHIMYE	Hopital GITWE, HC RUHANGO na d 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**	**Completed**

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4	**DIS/PSM/CT/20201105001**	ClustEr randomised Trial of sterile glove And instrument change at the time of wound closure to reduce surgical site infection [**CHEETAH]**	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 DHl, 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**	**Completed**
5	**DIS/PSM/CT/20200727001**	Clinical Study to Assess the treatment of Schizophrenia with Paliperidone Palmitate in Rwandan Helathcase settings **[CASPAR]**	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/RWANDAFDA/2021**	**Approved**	**12/16/2023**	**Ongoing Implementation**
6	**DIS/PSM/CT/20190926001**	INVestIgation of rheumatiC AFTreatment Using vitamin K antagonists, rivaroxaban or aspirin Studies **[INVICTUS]**	Population Health Research Institute Hamilton Health Sciences and McMaster University, Hamilton, Canada	Dr Emmnanuel RUSINGIZA	CHUK	Phase IV	Drugs	Vitamin K	32	**60 Months**	**029/RNEC/2021, 96/RNEC/2022**	**3/12/2022**	**Approved**	**3/11/2023**	**Completed**
7	**DIS/PSM/CT/20200090900 1**	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/RWANDAFDA/2021**	**Approved**	**5/31/2022**	**Stopped by Sponsor**
8	**DIS/PSM/CT/20201005001**	Preventing Pulmonary Complications in Surgical Patients at Risk of COVID-19 [**PROTECT-Surg]**	University of Birmingham	Prof NTIRENGANYA Faustin	CHUK, CHUB, Ruhengeri RH, Kibungo RH, Kibogora DH &Kibagabaga DH	Phase III	Drugs	**RESP301**	**300**	**12 Months**	**31/12/2020**	**003A/CT/RWANDA FDA/2020**	**Approved**	**2/1/2024**	**Suspended by Sponsor**

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9	**DIS/PSM/CT/20201116001**	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**	**18/06/2021**	**006/CT/RWANDA FDA/2021**	**Approved**	**3/14/2024**	**Closed out phase**
10	**DIS/PSM/CT/20201126002**	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**		**19/02/2021**	**005/CT/RWANDA FDA/2021**	**Approved**	**18/02/2022**	**Completed**
11	**DIS/PSM/CT/20201221002**	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**	**18/03/2021**	**007A/CT/RWANDA FDA/2021**	**Approved**	**10/22/2022**	**Completed**
12	**DIS/PSM/CT/20201211001**	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.HIV tetravalent vaccine, IM; Clade C gp140 monovalent vaccine, IM; Mosaic gp140 monovalent vaccine, IM**	**150**	**78 weeks**	**14/04/2021**	**001/CTA/RWANDA FDA/2021, 001R1/CTA/RWANDA FDA/2022,**	**Approved**	**10/4/2023**	**Completed**
13	**DIS/PSM/CT/20210115001**	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/RWANDA FDA/2021**	**Approved**	**7/6/2022**	**Completed**

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14	**DIS/PSM/CT/20210115001**	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 dihydroartemisinin-piperaquine tablet**	**528**	**18 months**	**1/6/2021**	**008/CT/RWANDA FDA/2021**	**Approved**	**11/8/2023**	**Ongoing Implementation**
15	**DIS/PSM/CT/20201125002**	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**	**10/29/2021**	**012/CTAC/FDA/2021**	**Approved**	**10/29/2022**	**Ongoing Implementation**
16	**DIS/PSM/CT/20210317**	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/CTAC/FDA/2021**	**Approved**	**12/8/2022**	**Stopped by Sponsor**
17	**DIS/PSM/CT/20211001**	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**	**12/30/2021**	**NA**	**Withdrawn**	**NA**	**Withdrawn**

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18	**DIS/PSM/CT/20211031001**	"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" **[DETACT]**	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/CTAC/FDA/2022**	**Approved**	**2/8/2024**	**Ongoing Implementation**
19	**DIS/PVSM/CT/20210907001**	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 **[INNOVATE]**	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**	**4/5/2022**	**NA**	**Withdrawn**	**NA**	**Withdrawn**
20	**DIS/PSM/CT/20221401**	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 **[CASSAVA LEAF]**	MycoBriah Ltd, USA	Dr. Menelas NKESHIMANA Centre, CHUK	CHUK, CHUB, GISENYI DH	NA	Other	**CASSAVA LEAF**	**49**	**12 months**	**4/21/2022**	**015/CTAC/FDA/2022**	**Approved**	**4/21/2023**	**Completed**
21	**DIS/PSM/CT/20220307001**	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**	**6/1/2022**	**016/CTAC/FDA/2022**	**Approved**	**6/6/2024**	**Ongoing Implementation**

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22	**DISP/SM/CT/20221401**	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	etc	Buranga Natural Honey	**98**	**24 months**	**6/17/2022**	**017/CTAC/FDA/2022**	**Approved**	**6/17/2023**	**Closed out phase**
23	**DIS/PSM/CT/20210820001**	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**	**6/17/2022**	**018/CTAC/FDA/2022**	**Approved**	**6/17/2023**	**Closed out phase**
24	**CTA-6411-2022**	VAC31518COV2004 An Open-label, Phase 2 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26.COV2.S 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.COV2.S (also known as Ad26COVS1), Monovalent vaccine	**400**	**21 months**	**8/5/2022**	**NA**	**Withdrawn**	**NA**	**Withdrawn**
25	**DIS/PSM/CT/20201211001**	Contrast-Enhanced Ultrasound in the Evaluation of Abdominal Solid Organ Injuries in Trauma Patients **[LUMASON]**	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**	**7/17/2022**	**NA**	**Withdrawn**	**NA**	**Withdrawn**
26	**DIS/PSM/CT/20210611001**	The impact of selenium Supplementation in the treatment of COVID 19 positive patients in Rwanda [**SELENIUM**]	NCST Rwanda & Selenium Education and Research Center SA	Dr. Kamwesiga Julius	King Faysal Hospital	Phase III	Drugs	Selenium supplement tablets	**100**	**38 weeks**	**9/28/2022**	**019/CTAC/FDA/2022**	**Approved**	**9/27/2023**	**Suspended by Authority**

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27	**DIS/PSM/CT/20220600200 1**	**[SPIKER/RW/CT/CTG-AI Version 02**] 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	Medical Devices	SPIKER AI-CTG (EDAN CTG F9)	**200**	**12 months**	**10/11/2022**	**020/CTAC/FDA/2022**	**Approved**	**10/10/2023**	**Suspended by Authority**
28	**DIS/PVSM/CT/CTA-16499-2022**	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**	**1/26/2023**	**021/CTAC/FDA/2023**	**Approved**	**1/25/2024**	**Stopped by Sponsor**
29	**DIS/PVSM/CT/CTA-15192-2023**	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**	**2/8/2023**	**022/CTAC/FDA/2023**	**Approved**	**2/7/2024**	**Ongoing Implementation**
30	**DIS/PVSM/CT/CTA-17687-2022**	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**	**2/15/2023**	**023/CTAC/FDA/2023**	**Approved**	**2/14/2024**	**Closed out phase**

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31	**DIS/PVSM/ CT/CTA-17687-2022**	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**	**4/27/2023**	**024/CTAC/1971-2023/FDA/1869/2023**	**Approved**	**10/26/2023**	**Stopped by Sponsor**
32	**DIS/PVSM/ CT/CTA-7482-2022**	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 Hydroclorothiazidum 40mg Olmesartanum medoxomilum / 10mg Amlodipinum/ 12.5mg Hydroclorothiazidum	**384**	**12 months**	**11/6/2023**	**025/CTA/7482-2023 /FDA/4670 /2023**	**Approved**	**11/5/2024**	**Ongoing Implementation**
33	**DIS/PVSM/ CT/CTA-6938-2023**	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**	**11/23/2023**	**028/CTAC/16938-2023/FDA/5260/2023**	**Approved**	**11/22/2023**	**Initiation Phase**
34	**RWANDA-FDA23/CTR /0005**	Building Respiratory support in East Africa Through High flow versus standard flow oxygen Evaluation.[**BREATHE]**	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	Phase III	Medical Devices	High Flow Oxygen (HFO) using Airvo2 device for oxygen delivery	**420**	**15 months**	**11/6/2023**	**026/CTA/0005/FDA/4672 /2023**	**Approved**	**11/5/2023**	**Initiation Phase**

Dr. Emile BIENVENU
Director General

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