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RWANDA FDA CLINICAL TRIAL REGISTER, UPDATE OF AUGUST 2021

No	Application reference Number	Title of the clinical trial	Name of Sponsor	Principal Investigator (PI)	Clinical Trial Site	Phase	Type of product (vaccine, drug, device)	Investigational Product (s)	Number of targeted trial participants	Trial duration	FDA Approval 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	NTIRENGAN YA 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	closed out phase
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	003/CT/RWANDA NDA FDA/2020	Approved	7/26/2022	Ongoing Implementation

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3	DIS/PSM/CT/20200404001	Clinical validation of Novel Malaria Diagnostic Tools for point of care testing [NOVEL MALARIA]	FIND Project/ Geneva, Switzerland	Mr MUSABYIMANA Jean Pierre and Dr NDISHIMYE Pacifique	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 NDA FDA/2021	Approved	6/22/2021	closed out phase
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 DH, Kabgayi DH, Kibogora DH, Gahini DH, Ejo Heza clinic	Phase IV	Medical Devices	Gloves	1580	12 Months	9/7/2020	002/CT/FDA/2020	Approved	8/11/2022	Ongoing Implementation
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 Bizoya, 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	011/CT/RWANDA NDA FDA/2021	Approved	23/06/2022	Ongoing Implementation
6	DIS/PSM/CT/20190926001	INVESTigation of rheumatoid Treatment Using vitamin K antagonists, rivaroxaban or aspirin Studies [INVICTUS]	Population Health Research Institute Hamilton Health Sciences and McMaster University, Hamilton, ON, Canada	Dr Emmanuel RUSINGIZA	CHUK	Phase IV	Drugs	Vitamin K	32	60 Months	029/RNEC/2021	2/8/2021	Approved	1/8/2022	Ongoing Implementation
7	DIS/PSM/CT/202000909001	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	1/6/2021	009/CT/RWANDA FDA/2021	Approved	31/05/2022	Ongoing Implementation

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8	DIS/PSM/CT/20201005001	Preventing Pulmonary Complications in Surgical Patients at Risk of COVID-19 [PROTECT-Surg]	University of Birmingham	Prof NTIRENGAN YA Faustin	University Teaching Hospital of Kigali, University Teaching Hospital of Butare, Ruhengeri Hospital, Kibungo Hospital, Kibogora Hospital	Phase III	Drugs	Hydroxychloroquine tablet 400mg	300	12 Months	31/12/2020	003/CT/RWA NDA FDA/2020	Approved	30/12/2021	Ongoing Implementation
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, 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/RWA NDA FDA/2021	Approved	17/06/2022	Ongoing Implementation
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/RWA NDA FDA/2021	Approved	18/02/2022	Ongoing Implementation
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	Home based	Phase II	Drugs	Prothione™ Capsules	200	44 Weeks	18/03/2021	007/CT/RWA NDA FDA/2021	Approved	17/03/2022	Ongoing Implementation

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12	DIS/PSM/CT/20201211001	Protocol Study Amendment: VAC89220HPX2003: 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.	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	Approved	13/04/2022	Ongoing Implementation
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, 114 East Main Street, Henderson, TN, USA	Dr. William Rutagengwa	Nyamata District Hospital, Nyamata Health Center	Phase III	Drugs	TriAntiMal™	50	4 months	8/6/2021	007/CT/RWANDA NDA FDA/2021	Approved	7/6/2022	Ongoing Implementation
14	DIS/PSM/CT/20210409001	Evaluation of the efficacy of artemether-lumefantrine and dihydroartemisinin-piperaquine in children with uncomplicated clinical malaria in Rwanda- [COARTEM-DDA-PIPERAQUINE]	PMI/Impact Malaria/ USAID	Dr. Anne Uwimana, Malaria Unit/RBC; Dr Noella Umulisa, Jhpiego, PMI Impact malaria	Rukara Health Center, Kayonza District Masaka Health Center, Kicukiro District	Phase IV	Drugs	Artemether-lumefantrine and dihydroartemisinin-piperaquine tablet	528	18 months	1/6/2021	008/CT/RWANDA NDA FDA/2021	Approved	31/05/2022	Ongoing Implementation

Done at KIGALI, on 30/08/2021

E. Bienvenu



Dr. Emile BIENVENU
Director General