Clinical Trials Registry at EDA

SN	Submission date	Study Code (Specified as per the submitted protocol)	Sponsor/CRO	Study title	Study type: -Interventional	Study Phase (I, II, III, or IV)	Sites/activation date "At which the clinical trials will be conducted in Egypt"	Status/date: -Approved - Recruiting -Recruitment completion -Completed -Withdrawn -Suspended -Terminated	Conditions / Therapeutic area	Interventions "Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)
1	27\12\2018	M15-991	Sponsor Abbvie	A multi-center, randomized, double-blind, placebo-controlled induction study to assess the efficacy and safety of Risankizumab in subjects with moderately to severely active Crohn's disease who failed prior biologic treatment	**Interventional**	III	1-CRC, faculty of medicine, Alexandria university 2-CRC, faculty of medicine, Alexandria university 3-Faculty of medicine, Cairo university 4- MASRI-CRC, Ain Shams University 5-National hepatology and tropical medicine institute 6-Faculty of medicine, Zagazig university	Approved 26/3/2019 Completed 3/11/2021	moderately to severely active Crohn's disease who failed prior biologic treatment	(Biological) Risankizumab

Color Indicator	
Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

Registry updated 02/04/2024

2	27\12\2018	M16-000	Sponsor Abbvie	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease who respond to induction treatment in M16-006 or M15-991 ; or completed M15-989	Interventional	III	Two sites at Faculty of Medicine, CRC, Alexandria University	Approved 26/3/2019 Recruiting	Crohn's disease	(Biological) Risankizumab
3	28\2\2019	M16-066	Sponsor Abbvie	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis	Interventional	III	1-Fcaulty of medicine, CRC, Alexandria University 2-CRC, Alexandria University 3-Air Force Specialized Hospital Research 4- National Liver Institute, Menoufia University	Approved 10/6/2019 Recruiting	Ulcerative Colitis	(Biological) Risankizumab
4	28\2\2019	M16-067	Sponsor Abbvie	Multicenter randomized double-blind placebo-controlled induction study to evaluate the	Interventional	III	1- CRC, faculty of medicine, Alexandria University	Approved 10/6/2019 Completed:	Active ulcerative colitis.	(Biological) Risankizumab

				efficacy and safety of Risankizumab in subjects with moderately to severely active ulcerative colitis.			2-National Liver Institute, Menoufia University 3-Air Force Specialized Hospital 4-Faculty of Medicine, CRC, Alexandria University	30/11/2023		
5	7/5/2019	QGE031	**Sponsor:** Novartis	A Multicenter, Randomized, double-blind active and placebo-controlled study to investigate the efficacy and safety of Ligelizumab in the treatment of chronic spontaneous urticaria in adolescents and adults in adequately controlled with H1 antihistamines	Interventional	III	1-Faculty of medicine, Alexandria university 2-Faculty of medicine, Ain Shams University	Withdrawal 31/8/2020	Chronic spontaneous Urticaria	(Biological) Ligelizumab
6	18/9/2019	ARTEMIS-DM “LPS15396 ”	SANOVI	A multicenter, multinational, prospective, interventional, single-arm, Phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300	Interventional	IV	1-Faculty of medicine, Alexandria university 2-CRC, Alexandria university 3-GOTHI 4-Faculty of medicine, Menoufia university	Approved 9/2/2020 Withdrawal	Type 2 diabetes mellitus	(Biological) Insulin glargine “Toujeo”

				U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin			5-Faculty of medicine, Ain Shams university			
7	18/11/2019	STAND	NOVARTIS	A phase II, multicenter, randomized, open label, two arm study comparing the effect of crizanlizumab+ SOC alone on renal function in sickle cell disease patients ≥16 years with chronic kidney disease due to sickle cell nephropathy	Interventional	II	1-Abu El Resh Children Hospital	Approved 5/5/2020 Withdrawal 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab
8	24/3/2020	STEAD FAST	Sponsor: Novartis	A Phase III, multicenter, double-blind study to assess efficacy and safety of two doses of crizanlizumab vs placebo with or without hydroxyurea / hydroxycarbamide therapy, in adolescent and adult sickle cell disease patients with vaso-occlusive crisis	Interventional	III	1-Faculty of medicine, Alexandria university 2-Faculty of medicine, Ain Shams university	Approved 20/2/2020 Withdrawal 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab
9	30/3/2020	WA40404	ROCHE	A Phase III b Multicenter,	Interventional	IIIb	1-Sayed Galal Hospital	Approved 23/8/2020	Primary progressive	(Biological)

				Randomized, double-blind, Placebo-controlled study to evaluate the efficacy and safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis			2-Faculty of medicine, Alexandria university 3-CRC, MASRI, Ain Shams University	Withdrawal 25/8/2021	multiple sclerosis	Ocrelizumab
10	14\9\2020	1368-0025	Boehringer Ingelheim	Open label long term extension study to assess the safety and efficacy of BI655130 treatment in patients with generalized pustular psoriasis	Interventional	IIb	1-Dermatology department, faculty of medicine, Alexandria university hospital	Approved 18/5/2021 Withdrawal 31/10/2021	Generalized pustular psoriasis	(Biological) Spesolimab
11	21/9/2020	05-Gam-COVID-Vac-2020	**Sponsor:** Russian Direct Investment Fund (RDIF)	A Phase III, randomized, double blind, placebo-controlled trial to evaluate immunogenicity and safety of the Gam-COVID-Vac combined vector vaccine in prophylactic treatment for SARS-COV-2 infection in Egypt	Interventional	III	1-National liver institute, Menoufia university 2-CRC, faculty of medicine, Alexandria university 3- CRC, MASRI, Ain Shams University	Withdrawn 12/6/2022	COVID-19 prophylaxis	(Biological) Russian Gam-COVID-Vac Combine vector vaccine
12	22/9/2020	CNBG202 0003SQ	China National Biotec	Multicenter, Randomized, Double blind,	Interventional	III	1-Vacsera Health care facility	Approved 28/3/2022	COVID-19 Prophylaxis	(Biological)

			Group company limited Wuhan institute of biological products Co. Ltd Beijin institute of biological products Co.Ltd	parallel placebo controlled, Phase III clinical trial to evaluate the protective efficacy, safety and immunogenicity of Inactivated SARS-COV-2 Vaccines in healthy population aged 18 years old and above			2-Ktameya medical center	Completed 31/7/2022		Inactivated SARS-COV-1 Vaccine
13	13/4/2021	D910DC00001 (Emerald-2)	Sponsor: AstraZeneca CRO: IQVIA	A phase 3 randomized double blind placebo controlled multicentre study of durvalumab monotherapy or in combination with bevacizumab as adjuvant therapy in patients with hepatocellular carcinoma who are at high risk of recurrence after	Interventional	III	1-CRC, Faculty of medicine, Alexandria University hospital 2-National Liver Institute-Menoufia University 3-National Hepatology & Tropical Medicine Research Institute 4-Air Force specialized Hospital	Approved 12/12/2021 Recruiting	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(Biological) Durvalumab\ Bevacizumab

				curative hepatic resection or ablation			5-Faculty of medicine, Assuit University			
14	19/5/2021	01-Sputnik-Light-2021	**Sponsor:** Human vaccine LLC (Global), Russian ministry of healthcare – Gamalya (Local) **CRO**: PDC	A phase III, randomized, double-blind, placebo-controlled international multi-site clinical trial in parallel assignment to evaluate efficacy, immunogenicity and safety of the Sputnik Light vector vaccine in adults in the SARS-Cov-2 infection prophylactic treatment	Interventional	III	1- National hepatology and tropical medicine center 2-Katemeya medical center	Approved 24/8/2021 Completion of study visit 31/8/2022	COVID-19 Prophylaxis	(Biological) Sputnik Light vector vaccine
15	25/5/2021	KATE-3	Sponsor: ROCHE	A randomized, multi-center, double blind, placebo-controlled phase III study of the efficacy and safety of Trastuzumab Emtansine in combination with Atezolizumab or placebo in Pts with HER2-positive and PD-L1- positive locally advanced or metastatic breast	Interventional	III	1-Faculty of medicine, Kasr Al-Ainy hospital 2-Shefaa Al-Orman hospital 3-Baheya Hospital	Approved 5/12/2021 Withdrawal 19/12/2022	HER2-positive and PD-L1-positive locally advanced or metastatic breast cancer	(Biological) Trastuzumab Emtansine/ Atezolizumab

				cancer who have received prior Trastuzumab + Atezolizumab and Taxane- based therapy						
16	27/5/2021	CAIN457P 12301	**Sponsor:** Novartis	A randomized, double blind, placebo-controlled, parallel group, phase III multi-center study of intravenous Secukinumab to compare efficacy at 16 weeks with placebo and to assess safety and tolerability up to 52 weeks in subjects with active ankylosis spondylitis of non-radiographic axial spondylo arthritis	Interventional	III	1-CRC, Faculty of medicine, Alexandrian university	Withdrawal 3/11/2021	Active ankylosis spondylitis	(Biological) Secukinumab
17	5/8/2021	TG2101V0 1	Sponsor: Livzon mabpharm Inc.	A Global, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Recombinant	Interventional	III	1-National Hepatology and Tropical Medicine Research Institute (NHTMRI)	Withdrawal 16/1/2022	COVID-19 Prophylaxis	(Biological) Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01)

				SARS-CoV-2 Fusion Protein Vaccine (V-01) in Adults Aged 18 Years and Older",						
18	18/8/2021	COVID_VACC_1	Sponsor: ROCHE	A phase III, open label, randomized study of Atezolizumab with Lenvatinib or Sorafenib versus Lenvatinib or sorafenib alone in hepatocellular carcinoma previously treated with Atezolizumab and Bevacizumab	Interventional	III	Air force specialized hospital	Approved 2/2/2022	Hepatocellular carcinoma	(Biological) Atezolizumab/ Lenvatinib/ Sorafenib
19	2/9/2021	COVID_VACC_1	Sponsor: National research center CRO: CLINMAX	A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Inactivated SARS-CoV-2 Vaccine Against COVID-19 in Healthy Adults	Interventional	I	National research center	Approved 9/11/2021 Suspended 9/12/2021	Covid-19 Prophylaxis	(Biological) Inactivated SARS-CoV-2 Vaccine
20	17/1/2022	SPHINX-EGYPT SPHINX22 122020	**Sponsor:** - EVA PHARMA - VSVRI - supreme council of	Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2	Interventional	I	Al-Manial specialized university Hospital, Cairo university hospitals	Approved 3/2/2022 Database lock 26/9/2023	Covid-19 Prophylaxis	(Biological) EgyVax

			university hospitals - Ministry of higher education and scientific research CRO: Dataclin	Infection (COVID-19)						
21	4/11/2021	GBT2104-131	Sponsor: Global blood therapeutics Inc. \ Pfizer CRO: MCT	A randomized double blinded placebo controlled multicentre study to access the safety and efficacy of Inclacumab in participants with sickle cell disease experiencing Vaso-occlusive crisis	Interventional	III	1-Faculty of medicine, Mansoura University 2-Faculty of medicine, Zagazig University 3-MASRI-CRC, Faculty of medicine, Ain Shams University hospital 4-CRC, Alexandria University 5- Pediatric hematology department, Alexandria University 6. CRC, faculty of medicine, Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University	Approved 14/6/2022 Recruitment completion	sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab

							8- Hematology department, Cairo University hospital			
22	4/1/2022	GBT2104-132	Global blood therapeutics Inc.\ Pfizer CRO: MCT	A Randomized, Double-blind, Placebo-controlled, Multicenter Study of a Single Dose of Inclacumab to Reduce Re-admission in Participants with Sickle Cell Disease and Recurrent Vaso-occlusive Crises (GBT-132)	Interventional	III	1. Faculty of medicine, Mansoura University 2. Faculty of medicine, Zagazig University 3. MASRI, CRC, Ain Shams University 4.Hematology unit, Internal medical department, CRC, faculty of medicine Alexandria University hospital 5- Hematology department, Alexandria University hospital 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.	Approved 14/6/2022 Withdrawal 29/6/2023	Sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab
23	28/11/2021	GBT2104-133	Global blood therapeutic	An Open-label Extension Study to Evaluate the Long-term Safety of	Interventional	III	1. Faculty of medicine, Mansoura University	Approved 14/6/2022 Withdrawal	sickle cell disease	(Biological) Inclacumab/

			s Inc.\ Pfizer CRO: MCT	Inclacumab Administered to Participants with Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial			2. Faculty of medicine, Zagazig University 3. MASRI, CRC, Ain Shams University 4.Hematology unit, Internal medical department, CRC, faculty of medicine Alexandria University hospital 5- Hematology department, Alexandria University hospital 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.	17/12/2023		Placebo
24	8\6\2022	Consonance-MN39159	**Sponsor:** F.HOFFMANN-LA ROCHE LTD **CRO:** Roche Egypt LLC & IQVIA	An open-label, single-arm 4-year study to evaluate effectiveness and safety of ocrelizumab treatment in patients with progressive multiple sclerosis	Interventional	III	1-CRC, Faculty of Medicine, Alexandria university, CRC 2-MASRI-CRC,faculty of medicine, Ain Shams university hospital	Approved 20/9/2022 Recruiting	Progressive multiple sclerosis	(Biological) Ocrelizumab

			(for monitoring activities only)							
25	9\2\2022	20200404 (IMBCAM	Sponsor: Institute of Medical Biology Chinese Academy of Medical Sciences CRO: PDC	A randomized double-blinded placebo-controlled Phase III clinical trial of SARS-COV-2 vaccine inactivated (Vero cell) in adult aged 18 years and above	Interventional	III	1-Katemeya Medical Center 2- National Hepatology and tropical medicine institute	Withdrawal 24/2/2022	Covid-19 Prophylaxis	(Biological) Inactivated SARS-COV-2 vaccine
26	10/5/2022	TRISTARDS-0135-0347	Sponsor: Boehringer Ingelheim CRO: MCT	The TRISTARDS trial -ThRombolys is Therapy for ARDS A Phase IIb/III operationally seamless, open-label, randomized, sequential, parallel-group adaptive study to evaluate the efficacy and safety of daily intravenous alteplase treatment given up to 5 days on top of standard of care (SOC) compared with SOC alone, in patients with acute respiratory distress	Interventional	IIb/III	1.National Hepatology and Tropical Medicine Research Institute 2.Abbasia Fever Hospital 3.Imbaba Fever Hospital	Withdrawal 20/7/2022	Respiratory distress syndrome (ARDS) triggered by COVID-19	(Biological) Alteplase

				syndrome (ARDS) triggered by COVID-19.						
27	14/8/2022	CAIN457A 2310	**Sponsor:** Novartis **CRO:** MCT	A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous Secukinumab compared to placebo and etanercept (in a single blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis	Interventional	III	1-CRC, Faculty of Medicine, Alexandria university hospital 2-Dermatology department, faculty of Medicine, Ain Shams University hospital	Approved 4/12/2022 Early terminated by sponsor 31/3/2023	Treatments of severe chronic plaque psoriasis	**(**Biological) Secukinumab
28	8/11/2022	SCTV01E-MRCT-1	Sponsor: Sinocelltech CRO: PDC	A randomized double blind positive controlled phase III clinical trial to evaluate the efficacy and safety of SCTV01E (a covid-19alpha/beta/delta/omicron variants s-	Interventional	III	1-Katemya Medical Center 2-Egyptian Liver research institute and hospital	Withdrawal 14/1/2023	COVID-19 prophylaxis	(Biological) SCTV01E (a covid-19 alpha/beta/delta/ omicron variants s-trimmer vaccine) (Biological)

				trimmer vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18						
29	6/6/2023	FUZION CNTO1959CRD	**Sponsor** : Janssen **CRO** : MCT	A Phase 3, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease "FUZION CD"	Interventional	III	1.National Hepatology Tropical Medicine Research Institute 2.CRC, faculty of medicine Alexandria university hospital, (two sites) 3. Department of internal medicine, El Kasr Al Aini, Cairo University 4. MASRI CRC, faculty of medicine, Ain Shams University Hospital	Approved 13/8/2023	Fistulizing perianal Crohn's disease	Guselkumab (Biological)
30	MP-ADA1-01	14/5/2023	**Sponsor:** Minapharm **CRO:** CRS Clinical Research Services Berlin GmbH	A Phase I, randomized, double-blind, 2-arm, parallel group trial to compare pharmacokinetics of Adessia with EU-authorized Humira in healthy male and female participants"	Interventional	I	-CRS clinical research services, Berlin GmbH -CRS clinical research services, Mannheim GmbH	Approved 10/8/2023	Inflammatory disease (Biosimilar to Humira)	Adessia (Biological)

31	4/5/2023	MOM-M281-006	Sponsor: Janssen CRO: MCT	Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a Long-term Open-label Extension"	Interventional	II\III	-National Cancer Institute, Cairo university -Oncology center, Mansoura University Hospital -Department of internal medicine, Al Kasr al Eini, Cairo university -Naser institute hospital for research and treatment -CRC, faculty of medicine, Alexandria university Hospital -CRC, faculty of medicine, Ain shams university Hospital	Approved 19/7/2023	Warm Autoimmune Hemolytic Anemia	M281 (Biological)
32	9\10/2023 shift to amendment submission 26\12\2023	EMERALD-3) **D910VC00001**	**Sposor**: AstraZeneca CRO: IQIVIA	A Phase III, Randomiz Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in	Interventional	III	- Air Force specialized hospital - Oncology department, Faculty of medicine, Alex University - Egyptian liver Hospital - National Hepatology and Tropical Medicine Research Institute (NHTMRI)	Approved 8/2/2024	Locoregional Hepatocellular Carcinoma	(Biological) Durvalumab / Tremelimumab/ Lenvatinib /TACE

				Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)			- Shifa El orman Hospital			
33	not submitted officially	CERE-CAP	investigator - initiated	Efficacy of Cerebrolysin as an adjuvant therapy following mechanical thrombectomy in patients with large vessels occlusion stroke	Interventional	III	Neurology and psychiatry department, Ain Shams University Hospital	Terminated (by EDA) (15/1/2024)	occlusion stroke	(Biological) CEREBROLYSIN solution for IM or IV injection/ concentrate for solution for I.V. infusion
34	17/12/2020	CEGA230 B2404	**Sponsor: Novartis CRO: MCT**	A Phase IV Multicenter Open Label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of Egaten (Triclabandazole) in Patients 6 Years of Age or Older with Fascioliasis (Egaten)	Interventional	IV	1-Cairo University, Al Mounira Children Hospital, Pediatric Hepatology Unit. 2-Alexandria University, Faculty of Medicine, Clinical Research Center.	Approved 12/4/2021 Recruiting	Fascioliasis	(Pharmaceutical) Triclabandazole (Egaten)
35	22/12/2020	CLEE011 A3201C RIGHT Choice	**Sponsor: Novartis CRO: MCT**	A Phase II Randomized Study of the Combination of Ribociclib Plus Goserelin Acetate with Hormonal Therapy Versus	Interventional	II	1-Ain Shams University, Faculty of Medicine, Clinical Research Center, (MASRI – CRC)	Approved 14/10/2021 Completed 8/1/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy

				Physician Choice Chemotherapy in Premenopausal or Perimenopausal Patients with Hormone Receptor-Positive/HER2-Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study			2-Baheya Hospital Research Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center			
36	24/10/2021	M14-430	**Sponsor: Abbvie CRO: NA**	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease Who Completed the Studies M14-431 or M14-433	Interventional	III	1-Air Force Specialized Hospital 2-National Liver Institute Menoufiya University 3-Alexandria University, Faculty of Medicine, Clinical Research Center. 4-Ain Shams University, Faculty of Medicine, Clinical Research Center (MASRI-CRC).	Approved 7/7/2022 Recruitment Completion	Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo
37	26/10/2021	BO40336 ALINA	**Sponsor: Roche CRO: NA**	A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus	Interventional	III	1- Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine.	Approved 16/3/2022 Recruitment Completion	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy

				Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors ≥ 4 Cm) To Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer						
38	12/12/2021	Cl_Tr_171 22019 MIRACLE -ALA	**Sponsor: EVA Pharma CRO: MARC**	A Multicenter, Interventional, Two-Arm, Parallel-Group, Randomized, Double-Blinded, Placebo-Controlled, Phase IV Trial to Evaluate the Efficacy of Alpha-Lipoic Acid in the Treatment of Patients with Symptomatic Diabetic Polyneuropathy in Egypt	Interventional	IV	1- Alexandria University Hospital, Diabetes, Metabolism, and Lipidology Unit, Department of Internal Medicine. 2- Ain Shams University Hospital 3- Menoufiya University Hospital 4- Mansoura University, Intrinsic Specialized Hospital. 5- Beni-Suef University Hospital, Diabetes and Endocrinology Unit.	Approved 12/10/2022 Recruiting	Treatment of Symptomatic Diabetic Polyneuropathy	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo

39	12/12/2021	MK4482-013 MOVe-Ahead	**Sponsor: MSD CRO: NA**	A Phase 3 Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of MK-4482 for the Prevention of COVID-19 (Laboratory Confirmed SARS-COV 2 Infection with Symptoms) in Adults.	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Air Force Specialized Hospital. 3-National Hepatology and Tropical Medicine Research Institute. 4-Imbaba Fever Hospital. 5-National Center for Allergies and Chest Imbaba	Approved 18/1/2022 Completed 16/11/2022	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/ matching placebo
40	30/3/2022	GBT440-032	**Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI**	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Voxelotor (GBT440) in Pediatric Participants with Sickle Cell Disease (HOPE Kids 2)	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Alexandria University Clinical Research Center. 3- Al Mounira Children Hospital, Cairo University, 4-Zagazig University Hospital, Department of Pediatrics.	Approved 31/7/2022 Recruitment Completion	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo
41	18/4/2022	GBT440-034	**Sponsor: GBT (Subsidiary of Pfizer)**	An Open Label Extension Study of GBT440 Administered Orally	Interventional	III	1-Cairo University, Abu El Rich Hospital.	Approved 2/8/2022	Sickle Cell Disease	(Pharmaceutical) Voxelotor

			CRO: IQVIA	to Patients with Sickle Cell Disease who Have Participated in GBT440 Clinical Trials			2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center 4-Zagazig University Hospital, Department of Pediatrics.	Recruitment Completion		
42	17/5/2022	F901318/0032	**Sponsor: F2G CRO: IQVIA**	Open Label Single Arm Phase IIb Study of F901318 as Treatment of Invasive Fungal Infections Due to Lomentospora Prolificans, Seedosporium Spp., Aspengillus Spp., & other Resistant Fungi in Patients Lacking Suitable Alternative	Interventional	IIb	1-Mansoura University Oncology center 2-Alexandria University, Clinical Research Center 3-Nasser Institute 4-Ain Shams University Clinical Research Center, (MASRI – CRC) 5-Air Force specialized Hospital 6-National Cancer Institute 7-Cairo University Kasr Al-Eini, Hospital	Terminated (By Sponsor) 24/7/2022	Invasive Fungal Infection	(Pharmaceutical) Olorofim
43	12/6/2022	CLSYN.1702 (OASIS-9)	**Sponsor: Hamilton Health Science**	A 2x2 Factorial Randomized Controlled Trial of CoLchicine and	Interventional	III/IV	1-Mansoura University Hospital 2-Suez Canal University Hospital	Approved 24/7/2022	STEMI/Non-STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/

			CRO: Clinmax	spironolactonE in Patients With myocARdial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9			3-Fayoum General Hospital 4-Tamia Central Hospital 5-El Kharga Specialized Hospital 6-National Heart Institute	Recruitment Completion		matching placebo
44	15/6/2022	20140106	**Sponsor: Onyx Pharmaceuticals (Subsidiary of Amgen) CRO: IQVIA**	Phase 1b/2 Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia	Interventional	Ib/II	1-Children's Cancer Hospital 57357	Approved 23/8/2022 Withdrawn 19/6/2023	Relapsed or Refractory Acute Lymphoplastic Leukemia	(Pharmaceutical) Carfilzomib
45	18/7/2022	AG348-C-020	**Sponsor: Agios CRO: MCT**	A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Mitapivat in Subjects with Sickle Cell Disease	Interventional	II/III	1-Alexandria University Clinical Research Center 2-Zagazig University Hospital 3-Cairo University Hospital 4-Mansoura University Hospital 5-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 27/9/2022 Withdrawn 21/8/2023	Sickle Cell Disease	(Pharmaceutical) Mitapivat / matching placebo

46	26/7/2022	F901318/0041	**Sponsor: F2G CRO: IQVIA**	A Phase III, Adjudicator-Blinded, Randomised Study to Evaluate the Efficacy and Safety of Treatment with Olorofim Versus Treatment with Ambisome® Followed by Standard of Care (SOC) in Patients with Invasive Fungal Disease (IFD) Caused by Aspergillus Species	Interventional	III	1-Mansoura University Oncology Center 2-Alexandria University Clinical Research Center 3-Air Force specialized Hospital 4-Ain Shams University, Clinical Research Center (MASRI-CRC) 5-Zagazig University Hospital 6-National Cancer Institute 7-Cairo University Kasr Al Eini Hospital 8-Nasser Institute for Research and Treatment	Approved 11/10/2022	Invasive Fungal Disease caused by Aspergillus species	(Pharmaceutical) Olorofim / Ambisome
47	27/7/2022	APD334-202	**Sponsor: Arena Pharmaceuticals (Subsidiary of Pfizer)**	A Multicenter Randomized Double Blinded Parallel Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severe Active	Interventional	III	1-Alexandria University Clinical Research Center 2-Air Force Specialized Hospital 3-National Liver Institute 4-National Hepatology and Tropical Medicine Research Institute (NHTMRI)	Approved 23/8/2022 Recruiting	Moderately to Severe Active Crohn's Disease	(Pharmaceutical) Etrasimod / matching placebo

				Crohn's Disease (Etrasimod)			4-Cairo University Kasr Al-Eini Hospital 5-Egyptian Liver Research Institute and Hospital 6-Ain Shams University Hospital 7-Theodor Bilharz Research Institute			
48	7/8/2022	EFC17215 LEAP-2-MONO	**Sponsor: Sanofi CRO: NA**	A Phase 3, Multicenter, Multinational Randomized Double-Blind Double-Dummy, Active Comparator Study to Evaluate the Efficacy and Safety of Venglustat in Adult and Pediatric Patients with Gaucher Disease Type 3 (GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy	Interventional	III	1-Alexandria University Hospital Clinical Research Center	Approved 24/10/2022	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme
49	15/8/2022	AG348-C-017	**Sponsor: Agios CRO: MCT**	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study	Interventional	III	1-Cairo University Hospital	Approved 2/11/2022	Non-Transfusion-Dependent	(Pharmaceutical) Mitapivat / matching placebo

				Evaluating the Efficacy and Safety of Mitapivat in Subjects with Non–Transfusion-Dependent Alpha- or Beta-Thalassemia (ENERGIZE)			2-Ain Shams University Clinical Research Center MASRI-CRC	Withdrawn 26/6/2023	Alpha or Beta Thalassemia	
50	15/8/2022	AG348-C-018	**Sponsor: Agios CRO: MCT**	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Transfusion-Dependent Alpha- or Beta-Thalassemia (ENERGIZE-T)	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Approved 2/11/2022 Withdrawn 26/6/2023	Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
51	29/8/2022	4202-HEM-301	**Sponsor: Forma Therapeutics CRO: MCT**	An Adaptive, Randomized, Placebo-Controlled, Double-blind, Multi-center Study of Oral Etavopivat, a Pyruvate Kinase Activator in Patients with Sickle Cell Disease	Interventional	III	1- Alexandria University Clinical Research Center 2-Zagazig University Hospital 3-Cairo University Hospital 4-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 11/12/2022	Sickle Cell Disease	(Pharmaceutical) Etavopivat / matching placebo
52	29/9/2022	GO42784 LIDERA	**Sponsor: Roche**	A Phase III, Randomized, Open-Label, Multicenter	Interventional	III	1-Alexandria University Hospital	Approved 4/12/2022	Estrogen Receptor–Positive, Her2-	(Pharmaceutical)

			CRO: MCT	Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared with Physician's Choice of Adjuvant Endocrine Monotherapy in Patients with Estrogen Receptor−Positive, Her2-Negative Early Breast Cancer			2-Medical Research Institute, Alexandria University 3-Mansoura University Hospital 4-Cairo University Kasr Al- Ainy Hospital 5-Ain Shams University Demerdash Hospital 6- Dar El Salam Cancer Hospital 7- Sohag Oncology Center	Recruitment Completion	Negative Early Breast Cancer	Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy
53	16/11/2022	(ACTIV-2D/A5407)	**Sponsor: Shionogi CRO: IQVIA**	A Phase 3, Multicenter, Randomized, Double-Blind, 24-Week Study of the Clinical and Antiviral Effect of S-217622 Compared with Placebo in Non-Hospitalized Participants with COVID-19	Interventional	III	1-National Hepatology and Tropical Medicine Research Institute 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center, 4-Air Force Specialized Hospital 5-National Institute for Chest Allergy and Diseases 6-Imbaba Fever Hospital	Approved 31/1/2023 Withdrawn 26/9/2023	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo

54	28/11/2022	RBSC2161	**Sponsor: Salix pharmaceuticals CRO: IQVIA**	A Phase 2a Randomized, Double-Blind, Placebo-Controlled Study to Characterize the Pharmacokinetics and Pharmacodynamics of Rifaximin Novel Formulations in Patients with Sickle Cell Disease	Interventional	IIa	1-Cairo University Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Zagazig University Hospital 4-Cairo University Hospital 5-Alexandria University Clinical Research Center	Approved 5/2/2023 Withdrawn 6/11/2023	Sickle Cell Disease	(Pharmaceutical) Rifaximin / matching placebo
55	22/1/2023	AT/03A-017	Sponsor: Atea Pharmaceuti-cals CRO: Avicemer	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19	Interventional	III	1- National Hepatology and Tropical Medicine Research Institute	Approved: 15/10/2023	COVID-19	(Pharmaceutical) Bemnifosbuvir/matching Placebo
56	13/2/2023	ENRICH-AF	**Sponsor: Hamilton Health Science CRO: Clinmax**	Edoxaban for Intracranial Haemorrhage Survivors with Atrial Fibrillation (ENRICH- AF) Edoxaban 60/30mg once daily	Interventional	IV	1-Ain Shams University Clinical Research Center (MASRI-CRC) 2-Zagazig University Hospital 3-Fayoum General Hospital	Approved 10/5/2023 Recruiting	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban

							4-Tanta University Hospital 5-Mansoura University Hospital 6-Ain Shams Specialized Hospital 7-Alexandria University Clinical Research Center 8-Assuit University Hospital			
57	13/2/2023	GBT440-038	**Sponsor: GBT (Subsidiary of Pfizer)**	An Open-Label Extension Study of Voxelotor Administered Orally to Paediatric Participants with Sickle Cell Disease Who Have Participated in Voxelotor Clinical Trials	Interventional	III	1-Alexandria University Clinical Research Center 2- Zagazig University Hospital 3-Cairo University, Abu El Rich Hospital. 4- Ain Shams University, Faculty of Medicine CRC (MASRI).	Approved 30/3/2023 Recruiting	Sickle Cell Disease	(Pharmaceutical) Voxelotor
58	1/3/2023	GN41851 FENHANCE	**Sponsor: Roche CRO: NA**	A Phase III Multicentre, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with	Interventional	III	1-Alexandria University- Clinical Research Center	Approved 26/4/2023 Withdrawn 11/1/2024	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo

				Teriflunomide In Adult Patients with Relapsing Multiple Sclerosis. .						
59	6/3/2023	1305-0023 (FIBRONEER –ILD	**Sponsor: Boehringer Ingelheim CRO: IQVIA**	A Double Blind, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of BI 1015550 Over At Least 52 Weeks in Patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Aini Hospital	Approved 1/6/2023 Withdrawn 17/1/2024	Progressive Fibrosing Interstitial lung diseases (PF- ILDs)	(Pharmaceutical) BI 1015550 / matching placebo
60	6/3/2023	1305-0014 (FIBRONEER – IPF)	**Sponsor: Boehringer Ingelheim CRO: IQVIA**	A Double Blind, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of BI 1015550 Over At Least 52 Weeks in Patients with Idiopathic Pulmonary Fibrosis (IPF)	Interventional	III	1- Ain Shams University Clinical Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Ainy Hospital	Approved 1/6/2023 Withdrawn 08/01/2024	Idiopathic Pulmonary Fibrosis (IPF)	(Pharmaceutical) BI 1015550 / matching placebo
61	16/3/2023	4202-HEM-201	**Sponsor: Forma Therapeutics CRO: MCT**	A Phase 2 Open-Label Study to Evaluate Safety and Clinical Activity of FT-4202 in Patients	Interventional	II	1- Cairo University, Abu El-Rich Children Hospital. 2-Cairo University, Kasr Al Eini Hospital.	Approved 1/6/2023	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat

				with Thalassemia or Sickle Cell Disease						
62	15/5/2023	EFC16035 (PERSEUS)	**Sponsor: Sanofi CRO: NA**	A Phase 3, Randomized, Double-Blind, Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis	Interventional	III	Alexandria University Clinical Research Center	Approved 10/8/2023	Primary Progressive Multiple Sclerosis	(Pharmaceutical) Tolebrutinib/ Matching Placebo
63	24/7/2022	MD-004	**Sponsor:** Ezz Medical Industries **CRO:**Data clin	Open labelled non randomized self-controlled study to evaluate the safety and performance of Ezvent in hospitalized mechanically ventilated patients	Interven3tional	III	1-Kasr Al-Aini university Hospital	Approved 28/8/2022 Suspended 1-1-2024 Resuming (ongoing) 13/1/2024	Hospitalized mechanically ventilated patients	Medical device (Ezvent)
64	15/5/2022	COAV101 B12301	Sponsor: Novartis CRO: MCT	A randomized sham controlled double – blind study to evaluate the efficacy and safety of intrathecal (IT) QAV101 in patients with later onset type 2 spinal muscular	Interventional	III	1-Department of Neurology, Ain Shams University Specialized Hospital.	Approved 2-8-2022 Early terminated (by sponsor) 18-12-2023	type 2 spinal muscular atrophy (SMA)	Innovative QAV101 (Zolgensma) (Onasemnogene abeparvovec)

				atrophy (SMA) who are ≥2 to <18 years of age, treatment naïve sitting and never ambulatory						
65	**6/6/2023**	Urso-003	Sponsor: Minapharm CRO: Nagy Research	Multi-Center, randomized, control, phase IV trial to compare the efficacy & safety of Ursoplus® capsules (UDCA 250mg & Silymarin 140mg) versus UDCA alone versus Placebo among Compensated Chronic Liver Disease Patients	Interventional	IV	Clinical Research Center, Air force specialized Hospital	Approved 18-9-2023 Recruiting	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/ Ursofalk® capsules
66	**6/6/2023**	Cipro-001	Sponsor: Minapharm , CRO: Nagy Research	Single center, Open Label, controlled Study to assess the safety & efficacy of Oral Ciprodiazole ® Tablets (Ciprofolxacin/ Metronidazole) versus currently used Ciprofloxacin Tablets & Metronidazole tablets in pelvi-abdominal infections and following IV antibiotics in post-	Interventional	IV	1- General Syrgery department, Menoufia University Hospital.	Suspended 12-9-2023	Pelvi-abdominal infections and following IV antibiotics in post-operative period, for pelvi-abdominal surgeries or acute conditions	Innovative Ciprodiazole ® Tablets (Ciprofolxacin/ Metronidazole)

				operative period, for pelvi-abdominal surgeries or acute conditions						
67	**15/5/2023**	Sub-Thromb-001	Sponsor: Minapharm CRO: NA	A Prospective, Single- Center, Phase IV Interventional, Single Arm Trial for the Evaluation of subcutaneous recombinant Hirudin 15 mg (RB variant) in prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations	Interventional	IV	1- Department of Orthopedics and Trauma Surgery, El-Hadra University Hospital	Withdrawal 28-8-2023	prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations	Innovative Thrombex (recombinant Hirudin)
68	**24/10/2023**	GRC/NE-CV/EG/39/IV	Sponsor: Nerhadou Internatio-nal CRO: Genuine research center	A prospective, Multicentre, Open-label, Single-arm Interventional Study of Bisoprolol (Nerkardou) (Between Low Dose and High Dose) 5 and 10 mg ODF Treatment In Egyptian Patients with Essential Hypertension	Interventional	IV	1- Department of General Internal Medicine , Beni-Suef University Hospital 2- Department of Cardiology and vascular medicine , Fayoum University Hospital	Approved 10-3-2024	Essential Hypertension	Innovative Nerkardou (Bisoprolol) Oral dispersible film