Clinical Trials Registry at EDA

SN	Study Code (Specified as per the submitted protocol)	Study title	Study type: -Interventional -Observational	Study Phase (I, II, III, or IV)	Sites "At which the clinical trials will be conducted in Egypt"	Status: -Approved -Ongoing -Suspended -Terminated -Completed -Withdrawal	Conditions / Therapeutic area	Interventions "Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)
1.	M15-991	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, Alexandria university 2-CRC, Alexandria university 3-Faculty of medicine, Cairo university 4- MASRI-CRC, Ain Shams University 5-NHTMRI 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
2.	M16-000	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 Ongoing	Crohn's disease	(Biological) Risankizumab

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

Registry updated 02/01/2024

3.	M16-066	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, Alexandria University 2-CRC, Alexandria University 3-Air Force Specialized Hospital Research 4- National Liver Institute, Menoufia University	Approved 10/6/2019 Ongoing	Ulcerative Colitis	(Biological) Risankizumab
4.	M16-067	Multicenter randomized double-blind placebo-controlled induction study to evaluate the efficacy and safety of Risankizumab in subjects with moderately to severely active ulcerative colitis.	Interventional	III	1- CRC, Alexandria University 2-National Liver Institute, Menoufia University 3-Air Force Specialized Hospital 4-Faculty of Medicine, Alexandria University	Approved 10/6/2019 Completed: 30/11/2023	Active ulcerative colitis.	(Biological) Risankizumab
5.	QGE031	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.	ARTEMIS -DM "LPS1539 6"	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 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin	Interventional	IV	1-Faculty of medicine, Alexandria university 2-CRC, Alexandria university 3-GOTHI 4-Faculty of medicine, Menoufia university 5-Faculty of medicine, Ain Shams univeristy	Approved 9/2/2020 Withdrawal	Type 2 diabetes mellitus	(Biological) Insulin glargine "Toujeo"
7.	STEAD FAST	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.	STAND	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.	WA40404	A Phase III b Multicenter, Randomized, double-blind, Placebo-controlled study to evaluate the efficacy and safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis	Interventional	IIIb	1-Sayed Galal Hospital 2-Faculty of medicine, Alexandria university 3-CRC, MASRI, Ain Shams University	Approved 23/8/2020 Withdrawal 25/8/2021	Primary progressive multiple sclerosis	(Biological) Ocrelizumab
10.	1368-0025	Open label long term extension study to assess the safety and efficacy of BI655130 treatment in patients with generalized pustular psoriasis	Interventional	IIb	1-Alexandria university hospital/ Dermatology department	Approved 18/5/2021 Withdrawal 31/10/2021	Generalized pustular psoriasis	(Biological) Spesolimab
11.	05-Gam-COVID-Vac-2020	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, Alexandria university 3- CRC, MASRI, Ain Shams University	Withdrawn 12/6/2022	COVID-19 prophylaxis	(Biological) Russian Gam-COVID-Vac Combine vector vaccine
12.	CNBG2020003SQ	Multicenter, Randomized, Double blind, parallel placebo controlled, Phase III clinical trial to evaluate the protective efficacy, safety and immunogenicity of Inactivated SARS-COV-2 Vaccines in healthy	Interventional	III	1-Vacsera Health care facility 2-Ktameya medical center	Approved 28/3/2022 Completed 31/7/2022	COVID-19 Prophylaxis	(Biological) Inactivated SARS-COV-1 Vaccine

		population aged 18 years old and above						
13.	D910DC00001 (Emerald-2)	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 curative hepatic resection or ablation	Interventional	III	1-Alexandria University-CRC 2-National Liver Institute-Menoufia University 3-National Hepatology & Tropical Medicine Research Institute 4-Air Force specialized Hospital 5-Assuit University	Approved 12/12/2021 Ongoing	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(Biological) Durvalumab\ Bevacizumab
14.	01-Sputnik-Light-2021	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.	KATE-3	A randomized, multi-center, double blind, placebo-controlled phase III study of the efficacy and safety of Trastuzumab Emtansine in	Interventional	III	1-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	(Biological) Trastuzumab Emtansine/ Atezolizumab

		combination with Atezolizumab or placebo in Pts with HER2-positive and PD-L1- positive locally advanced or metastatic breast cancer who have received prior Trastuzumab + Atezolizumab and Taxane-based therapy					advanced or metastatic breast cancer	
16.	CAIN457 P12301	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-Clinical research center, Alexandrian university	Withdrawal 3/11/2021	Active ankylosis spondylitis	(Biological) Secukinumab
17.	TG2101V 01	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-	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)

		01) in Adults Aged 18 Years and Older",						
18.	MO42541 IMPRAVE	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.	COVID_VACC_1	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.	SPHINX-EGYPT SPHINX2 2122020	Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2 Infection (COVID-19)	Interventional	I	Al-Manial specialized university Hospital	Approved 3/2/2022 Database lock 26/9/2023	Covid-19 Prophylaxis	(Biological) EgyVax
21.	GBT2104-131	A randomized double blinded placebo controlled multicentre study to access the safety and efficacy of Inclacumab in participants with sickle cell	Interventional	III	1-Faculty of medicine, Mansoura University 2-Faculty of medicine, Zagazig University 3-MASRI-CRC,Ain Shams University	Approved 14/6/2022 Ongoing	sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab

		disease experiencing Vaso-occlusive crisis			4-CRC,Alexandria University 5- Alexandria University, Hematology department 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.			
22.	GBT2104-132	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.CRC, Alexandria University 5- Alexandria University, Hematology department 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.	GBT2104-133	An Open-label Extension Study to Evaluate the Long-term Safety of Inclacumab Administered to Participants with Sickle Cell Disease Who	Interventional	III	1-Faculty of medicine, Mansoura University 2- Faculty of medicine, Zagazig University 3- CRC, MASRI, Ain Shams University	Approved 14/6/2022 Withdrawal 17/12/2023	sickle cell disease	(Biological) Inclacumab/ Placebo

		Have Participated in an Inclacumab Clinical Trial			4-CRC,Alexandria University 5- Alexandria University, Hematology department 6- Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.			
24.	Consonance-MN39159	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-Faculty of Medicine, Alexandria university, CRC 2-MASRI, Ain Shams university, CRC	Approved 20/9/2022 Ongoing	Progressive multiple sclerosis	(Biological) Ocrelizumab
25.	20200404 (IMBCAM)	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-Tropical Medicine Department, National Hepatology	Withdrawal 24/2/2022	Covid-19 Prophylaxis	(Biological) Inactivated SARS-COV-2 vaccine
26.	TRISTARDS-0135-0347	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	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

		treatment given up to 5 days on top of standard of care (SOC) compared with SOC alone, in patients with acute respiratory distress syndrome (ARDS) triggered by COVID-19.						
27.	CAIN457 A2310	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-Faculty of Medicine, Clinical Research Center 2-Faculty of Medicine, Dermatology Department, Ain Shams University	Approved 4/12/2022 Early terminated by sponsor 31/3/2023	Treatments of severe chronic plaque psoriasis	**(**Biological) Secukinumab
28.	SCTV01E -MRCT-1	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-trimmer vaccine) in population previously	Interventional	III	1-Katemya Medical Center 2-Egyptian Liver Hospital- Mansoura	Withdrawal 14/1/2023	COVID-19 prophylaxis	(Biological) SCTV01E (a covid-19 alpha/beta/delta/ omicron variants s-trimmer vaccine) (Biological)

		unvaccinated with COVID-19 vaccine and aged ≥18						
29.	FUZION CNTO1959CRD	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	-National Hepatology Tropical Medicine Research Institute 6/9/2023 -CRC, Alexandria university hospital -El Kasr Alinini,Cairo University -MASRI CRC, Ain Shams University Hospital	Approved 13/8/2023	Fistulizing perianal Crohn's disease	Guselkumab (Biological)
30.	MP-ADA1-01	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.	MOM-M281-006	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 -Oncology center, Mansoura University Hospital: -Al Kasr al Eini, Cairo university -Naser institute hospital for research and treatment	Approved 19/7/2023	Warm Autoimmune Hemolytic Anemia	M281 (Biological)

					-CRC, Alexandria university Hospital -CRC, Ain shams university Hospital			
32.	EMERALD -3)	A Phase III, Randomized, Open-Label, Sponsor-Blinded , Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)	Interventional	III	- Air Force specialized hospital - Oncology department, Faculty of medicine, Alex University - Egyptian liver Hospital - National Hepatology and Tropical Medicine Research Institute (NHTMRI) - Shifa El orman Hospital	Open	Locoregional Hepatocellular Carcinoma	(Biological) Durvalumab / Tremelimumab/ Lenvatinib /TACE
33.	CERE-CAP	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	Terminate (15/1/2024)	occlusion stroke	(Biological) CEREBROLYSIN solution for IM or IV injection/ concentrate for solution for I.V. infusion
34.	CEGA230 B2404	A Phase IV Multicenter Open Label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of Egaten	Interventional	IV	1-Cairo University, Al Mounira Children Hospital 2-Alexandria University Clinical Research Center.	Approved 12/4/2021 Ongoing	Fascioliasis	(Pharmaceutical) Triclabandazole (Egaten)

		(Triclabandazole) in Patients 6 Years of Age or Older with Fascioliasis (Egaten)						
35.	CLEE011 A3201C RIGHT Choice	A Phase II Randomized Study of the Combination of Ribociclib Plus Goserelin Acetate with Hormonal Therapy Versus Physician Choice Chemotherapy in Premenopausal or Perimenopausal Patients with Hormone Receptor-Positive/HER2-Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study	Interventional	II	1-Ain Shams University Clinical Research Center, (MASRI – CRC) 2-Baheya Hospital Research Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center	Approved 14/10/2021 Completed 8/1/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy
36.	BO40336 ALINA	A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus 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	Interventional	III	1-Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine	Approved 29/5/2019 Ongoing	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy

37.	Cl_Tr_17122019 MIRACLE-ALA	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 2-Ain Shams University Hospital 3-Menoufiya University Hospital 4-Mansoura University Hospital 5-Beni Suif University Hospital	Approved 12/10/2022 Ongoing	Treatment of Symptomatic Diabetic Polyneuropathy	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo
38.	M14-430	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 Clinical Research Center 4-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 2/12/2018 Ongoing	Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo
39.	MK4482-013 MOVe-Ahead	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	Approved 18/1/2022 Completed 16/11/2022	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/ matching placebo

					5-National Center for Allergies and Chest Imbaba			
40.	GBT440-032	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-Cairo University Hospital. 4-Zagazig University Hospital.	Approved 31/7/2022 Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo
41.	GBT440-034	An Open Label Extension Study of GBT440 Administered Orally to Patients with Sickle Cell Disease who Have Participated in GBT440 Clinical Trials	Interventional	III	1-Cairo University, Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center 4-Zagazig University Hospital.	Approved 2/8/2022 Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor
42.	F901318/0032	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)	Terminated (By Sponsor) 24/7/2022	Invasive Fungal Infection	(Pharmaceutical) Olorofim

					5-Air Force specialized Hospital 6-National Cancer Institute 7-Cairo University Kasr Al-Eini, Hospital			
43.	CLSYN.1702	A 2x2 factorial randomized controlled trial of CoLchicine and spironolactonE in patients with myocARdial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9	Interventional	III/IV	1-Mansoura University Hospital 2-Suez Canal University Hospital 3-Fayoum General Hospital 4-Tamia Central Hospital 5-El Kharga Specialized Hospital 6-National Heart Institute	Approved 24/7/2022 Ongoing	STEMI/Non-STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo
44.	20140106	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 Withdrawal 19/6/2023	Relapsed or Refractory Acute Lymphoplastic Leukemia	(Pharmaceutical) Carfilzomib
45.	AG348-C-020	A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Mitapivat in	Interventional	II/III	1-Alexandria University Clinical Research Center 2-Zagazig University Hospital 3-Cairo University Hospital	Approved 27/9/2022 Withdrawal 21/8/2023	Sickle Cell Disease	(Pharmaceutical) Mitapivat / matching placebo

		Subjects with Sickle Cell Disease			4-Mansoura University Hospital 5-Ain Shams University Clinical Research Center (MASRI-CRC)			
46.	F901318/0041	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.	APD334-202	A Multicentre Randomized Double Blinded Parallel Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for	Interventional	III	1-Alexandria University Clinical Research Center 2-Air Force Specialized Hospital 3-National Liver Institute 4-National Hepatology and Tropical Medicine	Approved 23/8/2022 Ongoing	Moderately to Severe Active Crohn's Disease	(Pharmaceutical) Etrasimod / matching placebo

		Moderately to Severe Active Crohn's Disease (Etrasimod)			Research Institute (NHTMRI) 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.	EFC17215 LEAP-2-MONO	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.	AG348-C-017	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Non–Transfusion-Dependent	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Approved 2/11/2022 Withdrawal 26/6/2023	Non-Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo

		Alpha- or Beta-Thalassemia (ENERGIZE)						
50.	AG348-C-018	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 Withdrawal 26/6/2023	Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
51.	4202-HEM-301	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.	GO42784 LIDERA	A Phase III, Randomized, Open-Label, Multicenter 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	Interventional	III	1-Alexandria University Hospital 2-Medical Research Institute, Alexandria University 3-Mansoura University Hospital 4-Cairo University Kasr Al- Ainy Hospital 5-Ain Shams University Demerdash Hospital	Approved 4/12/2022 Ongoing	Estrogen Receptor–Positive, Her2-Negative Early Breast Cancer	(Pharmaceutical) Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy

					6- Dar El Salam Cancer Hospital 7- Sohag Oncology Center			
53.	(ACTIV-2D/A5407)	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 Withdrawal 26/9/2023	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo
54.	RBSC2161	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 Withdrawal 6/11/2023	Sickle Cell Disease	(Pharmaceutical) Rifaximin / matching placebo

55.	ENRICH-AF	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 4-Tanta University Hospital 5-Mansoura University Hospital 6-Ain Shams Specialized Hospital 7-Alexandria University Clinical Research Center 8-Assuit University Hospital	Approved 10/5/2023 Ongoing	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban
56.	GN41851 FENHANCE	A phase III multicentre, randomized, double-blind, double-dummy, parallel-group study to evaluate the efficacy and safety of Fenebrutinib compared with Teriflunomide in adult patients with relapsing multiple sclerosis. .	Interventional	III	1-Alexandria University-Clinical Research Center	Approved 26/4/2023	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo
57.	1305-0023 (FIBRONEER – ILD)	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 1/6/2023	Progressive Fibrosing Interstitial lung diseases (PF- ILDs)	(Pharmaceutical) BI 1015550 / matching placebo

		Progressive Fibrosing Interstitial lung diseases (PF-ILDs)			2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Aini Hospital			
58.	1305-0014 (FIBRONEER – IPF)	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	Idiopathic Pulmonary Fibrosis (IPF)	(Pharmaceutical) BI 1015550 / matching placebo
59.	GBT440-038	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 Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor
60.	4202-HEM-201	A Phase 2 Open-Label Study to Evaluate Safety and Clinical Activity of FT-4202	Interventional	II	1- Cairo University, Abu El-Rich Children Hospital.	Approved 1/6/2023	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat

		in Patients with Thalassemia or Sickle Cell Disease			2-Cairo University, Kasr Al Eini Hospital.			
61.	EFC16035 (PERSEUS)	A Phase 3, Randomized, Double-Blind, Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis	Interventional	III	1-Alexandria University Clinical Research Center	Approved 10/8/2023	Primary Progressive Multiple Sclerosis	(Pharmaceutical) Tolebrutinib/Matching Placebo
62.	AT/03A-017	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 (Conditional Approval) 15/10/2023	Treatment of COVID-19	(Pharmaceutical) Bemnifosbuvir/Matching Placebo
63.	MD-004	Open labelled non randomized self-controlled study to evaluate the safety and performance of Ezvent in hospitalized mechanically ventilated patients	Interventional	III	1-Kasr Al-Aini university Hospital	Approved 28/8/2022 Suspended 1-1-2024 Resuming 13/1/2024	Hospitalized mechanically ventilated patients	Medical device (Ezvent)
64.	COAV101 B12301	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 atrophy (SMA) who are ≥2 to	Interventional	III	1-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)

		<18 years of age, treatment naïve sitting and never ambulatory						
65.	Urso-003	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	1-(Air force specialized Hospital)- AFSH	Approved 18-9-2023 Ongoing	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/ Ursofalk® capsules
66.	Cipro-001	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-operative period, for pelvi-abdominal surgeries or acute conditions	Interventional	IV	1-Menoufia University/ General Syrgery	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)
67.	Sub-Thromb-001	A Prospective, Single- Center, Phase IV Interventional, Single Arm Trial for the Evaluation of subcutaneous recombinant Hirudin 15 mg	Interventional	IV	1-Alexandria university (El-Hadra Hospital)	Withdrawal 28-8-2023	prophylaxis of Deep Vein Thrombosis (DVT) post major	Innovative Thrombex (recombinant Hirudin)

		(RB variant) in prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations					orthopedic operations	
68.	GRC/NE-CV/EG/39 /IV	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-Faculty of Medicine, Beni-Suef University Hospital	Open	Essential Hypertension	Innovative Nerkardou (Bisoprolol) Oral dispersible film