

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the clinical trials will be conducted in Egypt”	Status/date: -Approved - Recruiting -Recruitment completion -Completed -Withdrawn -Suspended -Terminated	Conditions / Therapeutic area	Interventions “Used IMPs & its type (Biological, Pharmaceutical , Innovative, Herbal, or medical device)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	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

							5-National hepatology and tropical medicine institute 6-Faculty of medicine, Zagazig university			
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	Interventional	III	Two sites at Faculty of Medicine, CRC, Alexandria University	Approved 26/3/2019 Recruitment completion	Crohn's disease	(Biological) Risankizumab

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Green	Biological
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				M15-989						
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 Recruitment completion	Ulcerative Colitis	(Biological) Risankizumab
4	28\2\2019	M16-067	Sponsor Abbvie	Multicenter randomized double-blind placebo-controlled induction study to evaluate the efficacy and safety of Risankizumab in subjects with	Interventional	III	1- CRC, faculty of medicine, Alexandria University 2-National Liver Institute, Menoufia University 3-Air Force	Approved 10/6/2019 Completed: 30/11/2023	Active ulcerative colitis.	(Biological) Risankizumab

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				moderately to severely active ulcerative colitis.			Specialized Hospital 4-Faculty of Medicine, CRC, Alexandria University			
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	Withdrawn 31/8/2020	Chronic spontaneous Urticaria	(Biological) Ligelizumab
6	18/9/2019	ARTEMI S-DM	SANOVI	A multicenter, multinational,	Interventional	IV	1-Faculty of medicine,	Approved 9/2/2020	Type 2 diabetes	(Biological)

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		"LPS1539 6"		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			Alexandria university 2-CRC, Alexandria university 3-GOTHI 4-Faculty of medicine, Menoufia university 5-Faculty of medicine, Ain Shams university	Withdrawn	mellitus	Insulin glargine "Toujeo"
7	18/11/2019	STAND	NOVART IS	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	Interventional	II	1-Abu El Resh Children Hospital	Approved 5/5/2020 Withdrawn 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab

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				kidney disease due to sickle cell nephropathy						
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 Withdrawn 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab
9	30/3/2020	WA40404	ROCHE	A Phase III b Multicenter, Randomized, double-blind, Placebo-controlled study to evaluate the efficacy and	Interventional	IIIb	1-Sayed Galal Hospital 2-Faculty of medicine, Alexandria university 3-CRC,	Approved 23/8/2020 Withdrawn 25/8/2021	Primary progressive multiple sclerosis	(Biological) Ocrelizumab

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				safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis			MASRI, Ain Shams University			
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 Withdrawn 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	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

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				SARS-COV-2 infection in Egypt						
12	22/9/2020	CNBG20 20003SQ	China National Biotec Group company limited Wuhan institute of biological products Co. Ltd Beijin institute of biological products Co.Ltd	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 population aged 18 years old and above	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
13	13/4/2021	D910DC0 0001	Sponsor: AstraZene	A phase 3 randomized	Interventional	III	1-CRC, Faculty of medicine,	Approved 12/12/2021	Hepatocellula r carcinoma	(Biological)

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		(Emerald-2)	ca CRO: IQVIA	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			Alexandria University hospital 2-National Liver Institute- Menoufia University 3-National Hepatology & Tropical Medicine Research Institute 4-Air Force specialized Hospital 5-Faculty of medicine, Assuit University	Recruitment completion	patients at high risk of recurrence after curative hepatic resection or ablation	Durvalumab\ Bevacizumab
14	19/5/2021	01-Sputnik-Light-2021	Sponsor: Human vaccine LLC (Global), Russian	A phase III, randomized, double-blind, placebo-controlled international multi-site clinical	Interventional	III	1- National hepatology and tropical medicine center 2-Katemeya medical center	Approved 24/8/2021 Completion of study visit	COVID-19 Prophylaxis	(Biological) Sputnik Light vector vaccine

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			ministry of healthcare – Gamalya (Local) CRO: PDC	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				31/8/2022		
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	Interventional	III	1-Faculty of medicine, Kasr Al-Ainy hospital 2-Shefaa Al- Orman hospital 3-Baheya Hospital	Approved 5/12/2021 Withdrawn 19/12/2022	HER2- positive and PD-L1- positive locally advanced or metastatic breast cancer	(Biological) Trastuzumab Emtansine/ Atezolizumab

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				advanced or metastatic breast cancer who have received prior Trastuzumab + Atezolizumab and Taxane- based therapy						
16	27/5/2021	CAIN457 P12301	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	Withdrawn 3/11/2021	Active ankylosing spondylitis	(Biological) Secukinumab

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17	5/8/2021	TG2101V01	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 SARS-CoV-2 Fusion Protein Vaccine (V-01) in Adults Aged 18 Years and Older",	Interventional	III	1-National Hepatology and Tropical Medicine Research Institute (NHTMRI)	Withdrawn 16/1/2022	COVID-19 Prophylaxis	(Biological) Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01)
18	18/8/2021	MO42541	Sponsor: ROCHE	A phase III, open label, randomized study of Atezolizumab with Lenvatinib or Sorafenib versus Lenvatinib or sorafenib alone in hepatocellular carcinoma	Interventional	III	Air force specialized hospital	Approved 2/2/2022 Recruitment completion	Hepatocellular carcinoma	(Biological) Atezolizumab/ Lenvatinib/ Sorafenib

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				previously treated with Atezolizumab and Bevacizumab						
19	2/9/2021	COVID_VACC_1	Sponsor: National research center CRO: CLINMA X	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 SPHINX2 2122020	Sponsor: - EVA PHARMA - VSVRI - supreme council of university hospitals - Ministry of higher education and scientific research	Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2 Infection (COVID-19)	Interventional	I	Al-Manial specialized university Hospital, Cairo university hospitals	Approved 3/2/2022 Database lock 26/9/2023	Covid-19 Prophylaxis	(Biological) EgyVax

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			CRO: Dataclin							
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,	Approved 14/6/2022 Recruitment completion	sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab

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							Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Hematology department, Cairo University hospital			
22	4/1/2022	GBT2104 -132	Global blood therapeuti cs 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,	Approved 14/6/2022 Withdrawn 29/6/2023	Sickle cell disease patients with Vaso- occlusive crisis	(Biological) Inclacumab

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							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.			
23	28/11/2021	GBT2104 -133	Global blood therapeu- tics Inc.\ Pfizer	An Open-label Extension Study to Evaluate the Long- term Safety of Inclacumab Administered to Participants with	Interventional	III	1. Faculty of medicine, Mansoura University 2. Faculty of medicine, Zagazig	Approved 14/6/2022 Withdrawn 17/12/2023	sickle cell disease	(Biological) Inclacumab/ Placebo

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			CRO: MCT	Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial			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,			
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							Hematology department.			
24	8\6\2022	Consonance-MN39159	Sponsor: F.HOFFMANN-LA ROCHE LTD CRO: Roche Egypt LLC & IQVIA (for monitoring activities only)	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 Recruitment completion	Progressive multiple sclerosis	(Biological) Ocrelizumab
25	9\2\2022	20200404 (IMBCAM)	Sponsor: Institute of Medical Biology Chinese Academy of Medical	A randomized double-blinded placebo-controlled Phase III clinical trial of SARS-COV-2 vaccine inactivated (Vero cell) in adult aged 18	Interventional	III	1-Katameya Medical Center 2- National Hepatology and tropical medicine institute	Withdrawn 24/2/2022	Covid-19 Prophylaxis	(Biological) Inactivated SARS-COV-2 vaccine

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			Sciences	years and above						
			CRO: PDC							
26	10/5/2022	TRISTAR DS- 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	Withdrawn 20/7/2022	Respiratory distress syndrome (ARDS) triggered by COVID-19	(Biological) Alteplase

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				syndrome (ARDS) triggered by COVID-19.						
27	14/8/2022	CAIN457 A2310	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

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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-trimmer vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18	Interventional	III	1-Katemya Medical Center 2-Egyptian Liver research institute and hospital	Withdrawn 14/1/2023	COVID-19 prophylaxis	(Biological) SCTV 01E (a covid-19 alpha/beta/delta/ omicron variants s-trimmer vaccine) (Biological)
29	6/6/2023	FUZION CNT019 59CRD	Sponsor: Janssen CRO: MCT	A Phase 3, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of	Interventional	III	1.National Hepatology Tropical Medicine Research Institute 2.CRC, faculty of medicine Alexandria	Approved 13/8/2023	Fistulizing perianal Crohn's disease	Guselkumab (Biological)

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				Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease "FUZION CD"			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			
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 Completed	Inflammatory disease (Biosimilar to Humira)	Adessia (Biological)

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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 Recruiting	Warm Autoimmune Hemolytic Anemia	M281 (Biological)
32	9\10/2023	EMERAL	Sponsor:	A Phase III,	Interventional	III	- Air Force	Approved	Locoregional	

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	shift to amendment submission 26\12\2023	D-3) D910VC0 0001	AstraZeneca CRO: IQIVIA	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)			specialized hospital - Oncology department, Faculty of medicine, Alex University - Egyptian liver Hospital - National Hepatology and Tropical Medicine Research Institute (NHTMRI) - Shifa El orman Hospital	8/2/2024 Recruiting	Hepatocellular Carcinoma	(Biological) Durvalumab / Tremelimumab/ Lenvatinib /TACE
33	not submitted officially	CERE-CAP	investigat or-initiated	Efficacy of Cerebrolysin as an adjuvant therapy following mechanical thrombectomy in patients with large	Interventional	III	Neurology and psychiatry department, Ain Shams University Hospital	Terminated (by EDA) (15/1/2024)	occlusion stroke	(Biological) CEREBROLYS IN solution for IM or IV injection/ concentrate for solution for I.V.

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				vessels occlusion stroke						infusion
34	14/12/2023	BCD-178	Sponsor: JSC BIOCAD CRO: Dataclin	A Double-Blind, Randomized Clinical Study of the Efficacy and Safety of BCD-178 and Perjeta® as Neoadjuvant Therapy of HER2-Positive Breast Cancer	Interventional	III	-Faculty of Medicine, Aleandria UNIVERSITY -Faculty of Medicine , Cairo University	Approved: 22/4/2024	Her-2 positive breast cancer	Biological BCD-178
35	8/1/2024	SerpinPc 102	Sponsor: Apcintex CRO: MCT	A Global, Open-label, Adaptive Design Study to Investigate the Efficacy and Safety of SerpinPC in Subjects with Severe Hemophilia A or Moderately Severe to Severe Hemophilia B (AP-0102)	Interventional	IIb	Ain Shams University Medical Research Institute (MASRI)	Approved 13/6/2024	Hemophilia A or Moderately Severe to Severe Hemophilia B	Biological SerpinPC 102

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36	8/1/2024	SerpinPC 103	Sponsor: Apcintex CRO: MCT	A Global, Open-label Study to Investigate the Efficacy and Safety of SerpinPC in Subjects with Hemophilia B with Inhibitors (AP-0103)	Interventional	IIb	Ain Shams University Medical Research Institute (MASRI)	Approved 13/6/2024	Hemophilia B with Inhibitors	Biological SerpinPC 103
37	8/2/2024	D9185C0001''TILI A'	Sponsor: AstraZenca CRO: IQIVIA	A Phase III, Multicenter, Randomized, Double-bind, Parallel-group, Placebo-Controlled study to evaluate the efficacy and safety of Tozoralimab (MEDI3506) in patients hospitalized for viral lung infection requiring supplemental oxygen	Interventional	III	1-Air Force specialized Hospital 2-Ain Shams University Medical research Institute (MASRI-CRC) 3-CRC, Alexandria University Hospital	Approved: 4/8/2024	Patients hospitalized for viral lung infection	Biological Tozoralimab

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37	17/12/2020	CEGA23 0B2404	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)
38	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 Physician Choice Chemotherapy in Premenopausal or Perimenopausal	Interventional	II	1-Ain Shams University, Faculty of Medicine, Clinical Research Center, (MASRI – CRC) 2-Baheya Hospital Research	Approved 14/10/2021 Completed 8/1/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy

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				Patients with Hormone Receptor- Positive/HER2- Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study			Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center			
39	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,	Approved 7/7/2022 Recruitment Completion	Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo

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							Clinical Research Center (MASRI-CRC).			
40	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 Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors $\geq$ 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 16/3/2022 Recruitment Completion	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy
41	12/12/2021	Cl_Tr_17 122019 MIRACL E-ALA	Sponsor: EVA Pharma CRO:	A Multicenter, Interventional, Two-Arm, Parallel-Group,	Interventional	IV	1- Alexandria University Hospital, Diabetes,	Approved 12/10/2022	Treatment of Symptomatic Diabetic Polyneuropat	(Pharmaceutical) Alpha-Lipoic Acid

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			MARC	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			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.	Recruiting	hy	(Thiotacid)/ matching placebo
42	12/12/2021	MK4482-013 MOVE-	Sponsor: MSD CRO: NA	A Phase 3 Multicenter, Randomized,	Interventional	III	1-Ain Shams University Clinical	Approved 18/1/2022	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/

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		Ahead		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.			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	Completed 16/11/2022		matching placebo
43	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	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Alexandria	Approved 31/7/2022 IMP Dosing Pause 02/05/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo

Color
Indicator

Green	Biological
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Orange	Medical Device
Gray	Innovative
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				Participants with Sickle Cell Disease (HOPE Kids 2)			University Clinical Research Center. 3- Al Mounira Children Hospital, Cairo University, 4-Zagazig University Hospital, Department of Pediatrics.	Early Termination 29/09/2024		
44	18/4/2022	GBT440-034	Sponsor: GBT (Subsidiary of Pfizer) CRO: IQVIA	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	Approved 2/8/2022 Early Termination 30/09/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor

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							Center 4-Zagazig University Hospital, Department of Pediatrics.			
45	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	Terminated (By Sponsor) 24/7/2022	Invasive Fungal Infection	(Pharmaceutical) Olorofim

Color
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							6-National Cancer Institute 7-Cairo University Kasr Al-Eini, Hospital			
46	12/6/2022	CLSYN.1 702 (OASIS- 9)	Sponsor: Hamilton Health Science CRO: Clinmax	A 2x2 Factorial Randomized Controlled Trial of Colchicine and spironolactone in Patients With myocardial infarction/SYNER GY 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 Completed	STEMI/Non- STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo
47	15/6/2022	20140106	Sponsor: Onyx Pharmaceuticals	Phase 1b/2 Study of Carfilzomib in Combination with Induction	Interventional	Ib/II	1-Children's Cancer Hospital 57357	Approved 23/8/2022	Relapsed or Refractory Acute Lymphoplasia	(Pharmaceutical) Carfilzomib

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			(Subsidiary of Amgen) CRO: IQVIA	Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia				Withdrawn 19/6/2023	c Leukemia	
48	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
49	26/7/2022	F901318/	Sponsor:	A Phase III,	Interventional	III	1-Mansoura	Approved	Invasive	(Pharmaceutical)

Color Indicator	Green	Biological
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		0041	F2G CRO: IQVIA	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			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	11/10/2022	Fungal Disease caused by Aspergillus species	Olorofim / Ambisome
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Color
Indicator

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							Institute for Research and Treatment			
50	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 Crohn's Disease (Etrasimod)	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) 4-Cairo University Kasr Al-Eini Hospital 5-Egyptian Liver Research Institute and	Approved 23/8/2022 Recruitment Completion	Moderately to Severe Active Crohn's Disease	(Pharmaceutical) Etrasimod / matching placebo

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							Hospital 6-Ain Shams University Hospital 7-Theodor Bilharz Research Institute			
51	7/8/2022	EFC1721 5 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	Interventional	III	1-Alexandria University Hospital Clinical Research Center	Approved 24/10/2022	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme

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				with Enzyme Replacement Therapy						
52	15/8/2022	AG348-C-017	Sponsor: Agios CRO: MCT	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Non-Transfusion-Dependent Alpha-or Beta-Thalassemia (ENERGIZE)	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Approved 2/11/2022 Withdrawn 26/6/2023	Non-Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
53	15/8/2022	AG348-C-018	Sponsor: Agios CRO: MCT	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research	Approved 2/11/2022 Withdrawn 26/6/2023	Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo

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				Safety of Mitapivat in Subjects with Transfusion-Dependent Alpha- or Beta- Thalassemia (ENERGIZE-T)			Center MASRI-CRC			
54	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 Recruiting	Sickle Cell Disease	(Pharmaceutical) Etavopivat / matching placebo
55	29/9/2022	GO42784 LIDERA	Sponsor: Roche	A Phase III, Randomized,	Interventional	III	1-Alexandria University	Approved 4/12/2022	Estrogen Receptor-Po	(Pharmaceutical)

Color Indicator

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			CRO: MCT	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			Hospital 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	sitive, Her2- Negative Early Breast Cancer	Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy
56	16/11/2022	(ACTIV- 2D/A540 7)	Sponsor: Shionogi CRO: IQVIA	A Phase 3, Multicenter, Randomized, Double-Blind, 24-	Interventional	III	1-National Hepatology and Tropical Medicine	Approved 31/1/2023 Withdrawn	Covid-19 treatment	(Pharmaceutical) S-217622 / matching

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				Week Study of the Clinical and Antiviral Effect of S-217622 Compared with Placebo in Non-Hospitalized Participants with COVID-19			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	26/9/2023		placebo
57	28/11/2022	RBSC2161	Sponsor: Salix pharmaceuticals CRO:	A Phase 2a Randomized, Double-Blind, Placebo-Controlled Study	Interventional	IIa	1-Cairo University Abu El Rich Hospital. 2-Ain Shams	Approved 5/2/2023 Withdrawn 6/11/2023	Sickle Cell Disease	(Pharmaceutical) Rifaximin / matching placebo

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			IQVIA	to Characterize the Pharmacokinetics and Pharmacodynamic s of Rifaximin Novel Formulations in Patients with Sickle Cell Disease			University Clinical Research Center (MASRI-CRC) 3-Zagazig University Hospital 4-Cairo University Hospital 5-Alexandria University Clinical Research Center			
58	22/1/2023	AT/03A-017	Sponsor: Atea Pharmace uti-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 Withdrawn 7/4/2024	COVID-19	(Pharmaceutical) Bemnifosbuvir/ matching Placebo

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59	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 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 Recruiting	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban
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Color
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60	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 IMP Dosing Pause 02/05/2024 Early Terminated by the Sponsor 26/9/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor
61	1/3/2023	GN41851 FENHAN CE	Sponsor: Roche CRO: NA	A Phase III Multicentre, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib	Interventional	III	1-Alexandria University-Clinical Research Center	Approved 26/4/2023 Withdrawn 11/1/2024	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo

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				Compared with Teriflunomide In Adult Patients with Relapsing Multiple Sclerosis.						
62	6/3/2023	1305-0023 (FIBRONER –ILD	Sponsor: Boehringer r 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
63	6/3/2023	1305-0014	Sponsor: Boehringer Ingelheim	A Double Blind, Randomized, Placebo-	Interventional	III	1- Ain Shams University Clinical	Approved 1/6/2023	Idiopathic Pulmonary Fibrosis	(Pharmaceutical) BI 1015550 /

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		(FIBRON EER – IPF)	CRO: IQVIA	Controlled Trial Evaluating the Efficacy and Safety of BI 1015550 Over At Least 52 Weeks in Patients with Idiopathic Pulmonary Fibrosis (IPF)			Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Ainy Hospital	Withdrawn 08/01/2024	(IPF)	matching placebo
64	16/3/2023	4202- HEM-201	Sponsor: Forma Therapeuti cs CRO: MCT	A Phase 2 Open- Label Study to Evaluate Safety and Clinical Activity of FT- 4202 in Patients with Thalassemia or Sickle Cell Disease	Interventional	II	1- Cairo University, Abu El-Rich Children Hospital. 2-Cairo University, Kasr Al Eini Hospital.	Approved 1/6/2023 Recruiting	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat
65	15/5/2023	EFC16035 (PERSEUS)	Sponsor: Sanofi CRO: NA	A Phase 3, Randomized, Double-Blind,	Interventional	III	Alexandria University Clinical	Approved 10/8/2023	Primary Progressive Multiple	(Pharmaceutical) Tolebrutinib/

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				Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis			Research Center	Withdrawn 15/4/2024	Sclerosis	Matching Placebo
66	14/3/2024	WO43571 HereDER A	Sponsor: Roche CRO: NA	A Phase III, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Giredestrant in Combination with Phesgo Versus Phesgo After Induction Therapy with Phesgo+ Taxane in Patients with Previously Untreated Her2-Positive, Estrogen Receptor-Positive	Interventional	III	1- Sohag Oncology Center 2- Dar El Salam Cancer Hospital 3- National Cancer Institute	Approved 8/4/2024 Recruiting	Previously Untreated Her2-Positive, Estrogen Receptor-Positive Locally-Advanced or Metastatic Breast Cancer	Pharmaceutical Giredestrant

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				Locally-Advanced or Metastatic Breast Cancer						
67	22/4/2024	1517-CL-1003	Sponsor: Astellas Pharma Global Developm ent CRO: MCT	A Phase 3, Open-label, Uncontrolled Study to Evaluate the Activity, Safety, Pharmacokinetics and Pharmacodynamic s of Roxadustat for the Treatment of Anemia in Pediatric Participants with Chronic Kidney Disease 1517-CL-1003	Interventional	III	1- Cairo University Children's Hospital 1- Ain Shams University Hospital 3- Alexandria University Hospital	Approved 10/7/2024 Withdrawn 26/9/2024	Anemia in Pediatric Patients with Chronic Kidney Disease	Pharmaceutical Roxadustat
68	5/6/2024	M23-698	Sponsor: Abbvie CRO: NA	A Phase 3, Randomized, Placebo- Controlled, Double-Blind Study to Evaluate	Interventional	III	1- Ain Shams University CRC (MASRI) 2- Air Force Specialized Hospital	Approved 7/8/2024	Moderate to Severe Hidradenitis Suppurativa	Pharmaceutical Upadacitinib

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				Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy M23-698			3- Alexandria University CRC			
67	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	Interventional	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)
68	15/5/2022	COAV10 1B12301	Sponsor: Novartis CRO:	A randomized sham controlled double –blind study to evaluate	Interventional	III	1-Department of Neurology, Ain Shams University	Approved 2-8-2022 Early	type 2 spinal muscular atrophy (SMA)	Innovative QAV101 (Zolgensma)

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			MCT	the efficacy and safety of intrathecal (IT) QAV101 in patients with later onset type 2 spinal muscular atrophy (SMA) who are ≥ 2 to < 18 years of age, treatment naïve sitting and never ambulatory			Specialized Hospital.	terminated (by sponsor) 18-12-2023		(Onasemnogene abeparvovec)
69	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 -National Hepatology and Tropical Research Institute (NHTMRI)	Approved 18-9-2023 Recruiting	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/ Ursofalk® capsules

Color
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70	6/6/2023	Cipro-001	Sponsor: Minapharm, CRO: Nagy Research	Single center, Open Label, controlled Study to assess the safety & efficacy of Oral Ciprofloxacin ® Tablets (Ciprofloxacin/ 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- General Surgery 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 Ciprofloxacin ® Tablets (Ciprofloxacin/ Metronidazole)
71	15/5/2023	Sub- Thromb- 001	Sponsor: Minapharm	A Prospective, Single- Center, Phase IV Interventional,	Interventional	IV	1- Department of Orthopedics and Trauma Surgery, El-	Withdrawn 28-8-2023	prophylaxis of Deep Vein Thrombosis (DVT) post	Innovative Thrombex (recombinant)

Color
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			CRO: NA	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			Hadra University Hospital		major orthopedic operations	Hirudin)
72	24/10/2023	GRC/NE- CV/EG/3 9/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 Recruiting	Essential Hypertension	Innovative Nerkardou (Bisoprolol) Oral dispersible film

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