



جمهورية مصر العربية هيئة الدواء المصرية الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الإكلينيكية الإدارة العامة للدراسات الإكلينيكية

إدارة البروتوكولات و متابعة إجراء الدراسات

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Clinical Trials Registry at EDA

SN	Submission date	Study Code (Specified as per the submitted protocol)	Sponsor/ CRO	Study title	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the clinical trials will be conducted in Egypt"	Status/date: -Approved - Recruiting -Recruitment completion -Completed -Withdrawn -Suspended -Terminated	Conditions / Therapeutic area	Interventions "Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)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	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	Approved 26/3/2019 Completed 3/11/2021	moderately to severely active Crohn's disease who failed prior biologic treatment	(Biological) Risankizumab

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





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						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 M15-989	III	Two sites at Faculty of Medicine, CRC, Alexandria University	Approved 26/3/2019 Recruitment completion 25/02/2021	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	III	1-Fcaulty of medicine, CRC, Alexandria University	Approved 10/6/2019 Recruitment completion 15/05/2023	Ulcerative Colitis	(Biological) Risankizumab

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5-	7/5/2019	QGE031	Sponsor: Novartis	A Multicenter, Randomized, double-blind active	III	1-Faculty of medicine,	Withdrawn 31/8/2020	Chronic spontaneous Urticaria	(Biological) Ligelizumab
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 moderately to severely active ulcerative colitis.	III	University 1- CRC, faculty of medicine, Alexandria University 2-National Liver Institute, Menoufia University 3-Air Force Specialized Hospital 4-Faculty of Medicine, CRC, Alexandria University	Approved 10/6/2019 Completed: 30/11/2023	Active ulcerative colitis.	(Biological) Risankizumab
				Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis		2-CRC, Alexandria University 3-Air Force Specialized Hospital Research 4- National Liver Institute, Menoufia			

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				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		Alexandria university 2-Faculty of medicine, Ain Shams University			
6-	18/9/2019	ARTEMI S-DM "LPS1539 6"	Sponsor: 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 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin	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 university	Approved 9/2/2020 Withdrawn 09/02/2020	Type 2 diabetes mellitus	(Biological) Insulin glargine "Toujeo"

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7-	18/11/2019	STAND	Sponsor: 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	II	1-Abu El Resh Children Hospital	Approved 5/5/2020 Withdrawn 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	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	Sponsor: ROCHE	A Phase III b Multicenter, Randomized,	IIIb	1-Sayed Galal Hospital	Approved 23/8/2020	Primary progressive	(Biological) Ocrelizumab

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				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	Withdrawn 25/8/2021	multiple sclerosis	
10-	14\9\2020	1368-0025	Sponsor: Boehringer Ingelheim CRO: MCT	Open label long term extension study to assess the safety and efficacy of BI655130 treatment in patients with generalized pustular psoriasis	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) CRO: RAY	A Phase III, randomized, double blind, placebocontrolled trial to evaluate immunogenicity and safety of the Gam-COVID-Vac combined vector vaccine in prophylactic treatment for SARS-COV-2 infection in Egypt	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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12-	22/9/2020	CNBG202 0003SQ	Sponsor: China National Biotec Group company limited Wuhan institute of biological products Co. Ltd Beijin institute of biological products Co.Ltd CRO:BDC	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	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 (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	Ш	1-CRC, Faculty of medicine, Alexandria University hospital 2-National Liver Institute-Menoufia University	Approved 12/12/2021 Recruitment completion 05-2022	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(Biological) Durvalumab\ Bevacizumab

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				hepatocellular carcinoma who are at high risk of recurrence after curative hepatic resection or ablation		3-National Hepatology & Tropical Medicine Research Institute 4-Air Force specialized Hospital 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 multisite 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	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

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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 cancer who have received prior Trastuzumab + Atezolizumab and Taxane- based therapy	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
16-	27/5/2021	CAIN457 P12301	Sponsor: Novartis CRO:MCT	A randomized, double blind, placebo-controlled, parallel group, phase III multi-center study of intravenous Secukinumab to compare efficacy at 16 weeks with	III	1-CRC, Faculty of medicine, Alexandrian university	Withdrawn 3/11/2021	Active ankylosing spondylitis	(Biological) Secukinumab

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				placebo and to assess safety and tolerability up to 52 weeks in subjects with active ankylosis spondylitis of non- radiographic axial spondylo arthritis					
17-	05/08/2021	TG2101V 01	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",	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-	18/08/2021	MO42541	Sponsor: ROCHE	A phase III, open label, randomized study of Atezolizumab with Lenvatinib or Sorafenib versus	III	Air force specialized hospital	Approved 2/2/2022 Recruitment completion 19/04/2024	Hepatocellular carcinoma	(Biological) Atezolizumab/ Lenvatinib/ Sorafenib

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				Lenvatinib or sorafenib alone in hepatocellular carcinoma previously treated with Atezolizumab and Bevacizumab					
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	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)	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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			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	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	Approved 14/6/2022 Completed: 30/5/2025	sickle cell disease patients with Vaso- occlusive crisis	(Biological) Inclacumab

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						7- CRC, Cairo University 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)	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	Approved 14/6/2022 Withdrawn 29/6/2023	Sickle cell disease patients with Vaso- occlusive crisis	(Biological) Inclacumab

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23-	28/11/2021	GBT2104 -133	Global blood therapeutics	An Open-label Extension Study to Evaluate the Long-	III	University hospital 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department. 1. Faculty of medicine, Mansoura	Approved 14/6/2022	sickle cell disease	(Biological) Inclacumab/
			Inc.\ Pfizer CRO: MCT	term Safety of Inclacumab Administered to Participants with Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial		University 2. Faculty of medicine, Zagazig University 3. MASRI, CRC, Ain Shams University 4.Hematology unit, Internal medical department, CRC, faculty of medicine Alexandria	Withdrawn 17/12/2023		Placebo

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24- 8\(Consonance- MN39159	Sponsor: F.HOFFMA NN-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	III	University hospital 5- Hematology department, Alexandria University hospital 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department. 1-CRC, Faculty of Medicine, Alexandria university, CRC 2-MASRI-CRC, faculty of medicine, Ain Shams university hospital	Approved 20/9/2022	Progressive multiple sclerosis	(Biological) Ocrelizumab
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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	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
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, openlabel, randomized, sequential, parallelgroup 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	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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				respiratory distress 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	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	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/

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				efficacy and safety of SCTV01E (a covid-19alpha/beta/delta/o micron variants strimmer vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18					omicron variants s-trimmer vaccine) (Biological)
29-	6/6/2023	FUZION CNTO1959 CRD	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"	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	Approved 13/8/2023 Recruiting	Fistulizing perianal Crohn's disease	Guselkumab (Biological)

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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"	I	medicine, Ain Shams University Hospital -CRS clinical research services, Berlin GmbH -CRS clinical research services, Mannheim GmbH	Approved 10/8/2023 Completed 04/2024	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 Longterm Open-label Extension"	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	Approved 19/7/2023 Early Terminated by the sponsor 21/02/2025	Warm Autoimmune Hemolytic Anemia	M281 (Biological)

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





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32-	9/10/2023 shift to amendment submission 26\12\2023	EMERAL D-3) D910VC0 0001	Sponsor: 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 Patients with Locoregional Hepatocellular	III	-CRC, faculty of medicine, Alexandria university Hospital -CRC, faculty of medicine, Ain shams university Hospital - 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 Recruiting	Locoregional Hepatocellular Carcinoma	(Biological) Durvalumab / Tremelimumab/ Lenvatinib /TACE
				Carcinoma (EMERALD-3)		- Shifa El Orman Hospital			

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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	III	Neurology and psychiatry department, Ain Shams University Hospital	Terminated (by EDA) (15/1/2024)	occlusion stroke	(Biological) CEREBROLYSI N solution for IM or IV injection/ concentrate for solution for I.V. 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	III	-Faculty of Medicine, Alexandria UNIVERSITY -Faculty of Medicine, Cairo University	Approved: 22/4/2024 Withdrawn: 25\12\2024	Her-2 positive breast cancer	(Biological) BCD-178
35-	8/1/2024	SerpinPc 102	Sponsor: Apcintex CRO: MCT	A Global, Openlabel, Adaptive Design Study to Investigate the Efficacy and Safety of SerpinPC in Subjects with Severe Hemophilia A or Moderately Severe to Severe Hemophilia B	IIb	Ain Shams University Medical Research Institute (MASRI)	Conditional Approved 13/6/2024 Final Approval 31/10/2024 Withdrawn: 16/01/2025	Hemophilia A or Moderately Severe to Severe Hemophilia B	(Biological) SerpinPC 102

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				(AP-0102)					
36-	8/1/2024	SerpinPC 103	Sponsor: Apcintex CRO: MCT	A Global, Openlabel Study to Investigate the Efficacy and Safety of SerpinPC in Subjects with Hemophilia B with Inhibitors (AP-0103)	IIb	Ain Shams University Medical Research Institute (MASRI)	Conditional Approved 13/6/2024 Final Approval 31/10/2024 Withdrawn: 16/01/2025	Hemophilia B with Inhibitors	(Biological) Serpin PC 103
37-		D9185C000 01" TILIA'	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 hospital;ized for viral lung infection requiring supplemental oxygen	III	1-Air Force specialized Hospital 2-Ain Shams University Medical Research Institute (MASRI-CRC) 3-CRC, Alexandria University Hospital	Approved: 4/8/2024 Withdrawn: 30/01/2025	Patients hospitalized for viral lung infection	(Biological) Tozoralimab
38-	16/01/2025	GA45329- Ametrine 1	Sponsor: Roche	A Phase III, Multicenter, Double-Blind,	III	Clinical Research Center, Internal	Approved: 10/03/2025	Patients with Moderately to Severely	(Biological) RO7790121

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				Placebo-Controlled, Treat-Through Study to Assess the Efficacy and Safety of Induction and Maintenance Therapy with RO7790121 In Patients with Moderately to Severely Active Ulcerative Colitis		Medicine Faculty of Medicine, Alexandria University		Active Ulcerative Colitis	
39-	16/01/2025	GA45330- Ametrine 2	Sponsor: Roche	A Phase III, Multicenter, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Induction Therapy with RO7790121 In Patients with Moderately to Severely Active Ulcerative Colitis	III	Clinical Research Center, Internal Medicine Faculty of Medicine, Alexandria University	Approved: 10/03/2025	Patients with Moderately to Severely Active Ulcerative Colitis	(Biological) RO7790121
40	11\5\2025	GA45331	Sponsor: Roche	A Phase III Multicenter Double- Blind Placebo Controlled Treat through study to	III	1-Clinical Research Center, Faculty of Medicine, Alexandria	Approved: 01\06\2025	Crohn's Disease	(Biological) RO7790121

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40-	17/12/2020	CEGA230 B2404	Sponsor: Novartis CRO: MCT	assess the efficacy and safety of Induction and Maintenance therapy with RO7790121 in patients with moderately to severely active Crohn's disease 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)	IV	University Hospital 2-Air Force Specialized Hospital 3-National Liver Institute, Menoufya University 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)
41-	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	II	1-Ain Shams University, Faculty of Medicine, Clinical	Approved 14/10/2021 Completed 8/1/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy

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42-	24/10/2021	M14-430	Sponsor: Abbvie	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 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	III	Research Center, (MASRI – CRC) 2-Baheya Hospital Research Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center 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		Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo
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						Research Center (MASRI-CRC).			
43-	26/10/2021	BO40336 ALINA	Sponsor: Roche	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	III	1- Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine.	Recruitment	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy
44-	12/12/2021	Cl_Tr_17 122019 MIRACL E-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	IV	1- Alexandri a University Hospital, Diabetes, Metabolism, and Lipidology Unit, Department of Internal Medicine.	Approved 12/10/2022 Completed 11/12/2024	Treatment of Symptomatic Diabetic Polyneuropath y	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo

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				Treatment of Patients with Symptomatic Diabetic Polyneuropathy in Egypt		2- Ain Shams University Hospital 3- Menoufiy a University Hospital 4- Mansoura University, Intrinsic Specialized Hospital. 5- Beni-Suef University Hospital, Diabetes and Endocrinology Unit.			
45-	12/12/2021	MK4482- 013 MOVe- Ahead	Sponsor: MSD	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	III	1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Air Force Specialized Hospital. 3-National Hepatology and Tropical Medicine	Approved 18/1/2022 Completed 16/11/2022	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/ matching placebo

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				with Symptoms) in Adults.		Research Institute. 4-Imbaba Fever Hospital. 5-National Center for Allergies and Chest Imbaba			
46-	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)	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 IMP Dosing Pause 02/05/2024 Early Termination by the sponsor 29/09/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo
47-		GBT440- 034	Sponsor: GBT (Subsidiary of Pfizer)	An Open Label Extension Study of GBT440 Administered Orally	III	1-Cairo University, Abu El Rich Hospital.	Approved 2/8/2022	Sickle Cell Disease	(Pharmaceutical) Voxelotor

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40 17/5/2022		CRO: IQVIA	to Patients with Sickle Cell Disease who Have Participated in GBT440 Clinical Trials	M	2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center 4-Zagazig University Hospital, Department of Pediatrics.	Early Termination by the sponsor 30/09/2024		
48- 17/5/2022	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	IIb	Pediatrics. 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

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50-	15/6/2022	20140106	Sponsor: Onyx Pharmaceut icals	myocARdial infarction/SYNERG Y Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9 Phase 1b/2 Study of Carfilzomib in Combination with Induction	Ib/II	3-Fayoum General Hospital 4-Tamia Central Hospital 5-El Kharga Specialized Hospital 6-National Heart Institute 1-Children's Cancer Hospital 57357	Approved 23/8/2022 Withdrawn	Relapsed or Refractory Acute Lymphoplastic	(Pharmaceutical) Carfilzomib
49-	12/6/2022	CLSYN.1 702 (OASIS- 9)	Sponsor: Hamilton Health Science	A 2x2 Factorial Randomized Controlled Trial of CoLchicine and spironolactonE in Patients With	III/IV	Al-Eini, Hospital 1-Mansoura University Hospital 2-Suez Canal University Hospital	Approved 24/7/2022 Completed 01/08/2024	STEMI/Non- STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo
						5-Air Force specialized Hospital 6-National Cancer Institute 7-Cairo University Kasr			

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of Amgen)

Children with

Relapsed or

Issue/ Rev No.: 3/0 QF: Bio Inn.231.01 Issue Date: 15/06/2025 **Rev Date: --/--/** Page 30 of 48





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			CRO: IQVIA	Refractory Acute Lymphoblastic Leukemia					
51-	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	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
52-	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	III	1-Mansoura University Oncology Center 2-Alexandria University Clinical Research Center	Approved 11/10/2022	Invasive Fungal Disease caused by Aspergillus species	(Pharmaceutical) Olorofim / Ambisome

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Maintenance

Therapy for



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					Ambisome®		3-Air Force			
					Followed by		specialized			
					Standard of Care		Hospital			
					(SOC) in Patients		4-Ain Shams			
					with Invasive		University,			
					Fungal Disease		Clinical			
					(IFD) Caused by		Research Center			
					Aspergillus Species		(MASRI-CRC)			
					1 0 1		5-Zagazig			
							University			
							Hospital			
							6-National			
							Cancer Institute			
							7-Cairo			
							University Kasr			
							Al Eini Hospital			
							8-Nasser			
							Institute for			
							Research and			
							Treatment			
Ī	53-	27/7/2022	APD334-	Sponsor:	A Multicenter	III	1-Alexandria	Approved	Moderately to	(Pharmaceutical)
			202	Arena	Randomized Double		University	23/8/2022	Severe Active	,
				Pharmaceut	Blinded Parallel		Clinical		Crohn's	Etrasimod /
				icals	Group Study to		Research Center	Recruitment	Disease	matching placebo
				(Subsidiary	Assess the Efficacy		2-Air Force	Completion		0.1
				of Pfizer)	and Safety of Oral		Specialized	•		
				,	Etrasimod as		Hospital	Early		
				CRO:IQVIA	Induction and		3-National Liver	Terminated by		
				,				,		

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20/03/2025





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				Moderately to Severe Active Crohn's Disease (Etrasimod)		4-National Hepatology and Tropical Medicine 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			
54-	7/8/2022	EFC1721 5 LEAP-2- MONO	Sponsor: Sanofi	A Phase 3, Multicenter, Multinational Randomized Double-Blind Double-Dummy, Active Comparator Study to Evaluate the Efficacy and Safety of Venglustat	III	1-Alexandria University Hospital Clinical Research Center	Approved 24/10/2022	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme

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				in Adult and Pediatric Patients with Gaucher Disease Type 3 (GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy					
55-	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 Alphaor Beta-Thalassemia (ENERGIZE)	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
56-	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	III	1-Cairo University Hospital 2-Ain Shams University Clinical	Approved 2/11/2022 Withdrawn 26/6/2023	Transfusion- Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo

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				Transfusion- Dependent Alpha- or Beta-Thalassemia (ENERGIZE-T)		Research Center MASRI-CRC			
57-	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	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 Recruitment Completion 17/01/2025	Sickle Cell Disease	(Pharmaceutical) Etavopivat / matching placebo
58-	29/9/2022	GO42784 LIDERA	Sponsor: Roche CRO: MCT	A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared with Physician's Choice of Adjuvant Endocrine	Ш	1-Alexandria University Hospital 2-Medical Research Institute, Alexandria University 3-Mansoura University Hospital	Approved 4/12/2022 Recruitment Completion 09/08/2023	Estrogen Receptor-Posi tive, Her2- Negative Early Breast Cancer	(Pharmaceutical) Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy

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





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				Monotherapy in Patients with Estrogen Receptor—Positive, Her2-Negative Early Breast Cancer		4-Cairo University Kasr Al- Ainy Hospital 5-Ain Shams University Demerdash Hospital 6- Dar El Salam Cancer Hospital 7- Sohag Oncology Center			
59-	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	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	Approved 31/1/2023 Withdrawn 26/9/2023	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo

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	Blue	Pharmaceutical
Color	Orange	Medical Device
Indicator	Gray	Innovative
	Red	Herbal

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هيئة الدواء المصرية الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الاكلينيكية

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						5-National Institute for Chest Allergy and Diseases 6-Imbaba Fever Hospital			
60-	28/11/2022	RBSC2161	Sponsor: Salix pharmaceuti cals 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	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
61-	22/1/2023	AT/03A- 017	Sponsor: Atea Pharmaceut i-cals	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and	III	1- National Hepatology and Tropical Medicine Research Institute	Approved: 15/10/2023 Withdrawn 7/4/2024	COVID-19	(Pharmaceutical) Bemnifosbuvir/m atching Placebo

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

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			CRO: Avicemer	Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19					
62-	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	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	Approved 10/5/2023 Recruitment Completion 31/10/2024	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban

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Color	Orange	Medical Device
Indicator	Gray	Innovative
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							8-Assuit University Hospital			
((63-	13/2/2023	GBT440- 038	Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI	An Open-Label Extension Study of Voxelotor Administered Orally to Paediatric Participants with Sickle Cell Disease Who Have Participated in Voxelotor Clinical Trials	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
	54-	1/3/2023	GN41851 FENHANC E	Sponsor: Roche	A Phase III Multicentre, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with	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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				Teriflunomide In Adult Patients with Relapsing Multiple Sclerosis.					
65-	6/3/2023	1305-0023 (FIBRONE ER –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)	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
66-	6/3/2023	1305- 0014 (FIBRON EER – 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)	III	1- Ain Shams University Clinical Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center	Approved 1/6/2023 Withdrawn 08/01/2024	Idiopathic Pulmonary Fibrosis (IPF)	(Pharmaceutical) BI 1015550 / matching placebo

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						3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Ainy Hospital			
67-	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 with Thalassemia or Sickle Cell Disease	П	1- Cairo University, Abu El-Rich Children Hospital. 2-Cairo University, Kasr Al Eini Hospital.	Approved 1/6/2023 Recruitment Completion	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat
68-	15/5/2023	EFC16035 (PERSEUS)	Sponsor: Sanofi	A Phase 3, Randomized, Double-Blind, Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis	III	Alexandria University Clinical Research Center	Approved 10/8/2023 Withdrawn 15/4/2024	Primary Progressive Multiple Sclerosis	(Pharmaceutical) Tolebrutinib/ Matching Placebo
69-	14/3/2024	WO43571 HereDER A	Sponsor: Roche	A Phase III, Randomized, Open- Label Study Evaluating the Efficacy and Safety	III	1- Sohag Oncology Center 2- Dar El Salam Cancer Hospital	Approved 8/4/2024	Previously Untreated Her2-Positive, Estrogen Receptor-	Pharmaceutical Giredestrant

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70-	22/4/2024	1517-CL- 1003	Sponsor: Astellas Pharma Global Development CRO: MCT	and Pharmacodynamics of Roxadustat for the Treatment of Anemia in Pediatric	III	3- National Cancer Institute 1- Cairo University Children's Hospital 1- Ain Shams University Hospital 3- Alexandria University Hospital	Approved 10/7/2024 Withdrawn 26/9/2024	Positive Locally- Advanced or Metastatic Breast Cancer Anemia in Pediatric Patients with Chronic Kidney Disease	Pharmaceutical Roxadustat
				the Treatment of		University			

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71-	5/6/2024	M23-698	Sponsor: Abbvie	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti- TNF Therapy	III	1- Ain Shams University CRC (MASRI) 2- Air Force Specialized Hospital 3- Alexandria University CRC	Approved 7/8/2024 Withdrawn 09/04/2025	Moderate to Severe Hidradenitis Suppurativa	Pharmaceutical Upadacitinib
72-	16/12/2024	DAY101- 002	Sponsor: Day One Biopharma ceuticals CRO: MCT	M23-698 A Phase 3, Randomized, International Multicenter Trial of DAY101 Monotherapy Versus Standard of Care Chemotherapy in Patients with Pediatric Low- Grade Glioma Harboring an Activating RAF Alteration Requiring	III	Children Cancer Hospital Egypt- 57357	Approved 20/02/2025	Pediatric Low- Grade Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy	Pharmaceutical Tovorafenib

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				First-Line Systemic				
				Therapy				
73-	29/01/2025	NN7535- 7822 FLORAL	Sponsor: Forma Therapeutics CRO: IQVIA	An open-label, multi-centre, rollover study to characterise long-term safety and efficacy of Etavopivat in adults, adolescents and children who have sickle cell disease or thalassaemia and have completed a treatment period in an etavopivat study	1- Alexandria University Clinical Research Center (PI: Prof. Hoda Hassab) 2-Alexandria University Clinical Research Center (PI: Prof. Ashraf El Ghandour) 3-Zagazig University Hospital 4-Kasr Al Aini Hospital, Cairo University 5-Ain Shams University Clinical Research Center (MASRI-CRC) 6- Abu El Rich Al Mounira Children Hospital, Cairo University	Approved 10/04/2025	Adults, adolescents and children who have sickle cell disease or thalassaemia	Pharmaceutical (Etavopivat)

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73-	24/7/2022	MD-004	Sponsor: Ezz Medical Industries CRO: Dataclin	Open labelled non randomized self-controlled study to evaluate the safety and performance of Ezvent in hospitalized mechanically ventilated patients	III (pivotal)	1- Critical care Unit, Kasr Elainy Hospital, Cairo University	Approved 28/8/2022 Suspended 1-1-2024 Resuming 13/1/2024 Completed 4/6/2025	Hospitalized mechanically ventilated patients	Medical device (Ezvent)
74-	15/5/2022	COAV10 1B12301	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 atrophy (SMA) who are ≥2 to <18 years of age, treatment naïve sitting and never ambulatory	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)
75-	6/6/2023	Urso-003	Sponsor: Minapharm	Multi-Center, randomized, control, phase IV trial to compare the	IV	Clinical Research Center, Air force	Approved 18-9-2023	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/

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			CRO: Dataclin	efficacy & safety of Ursoplus® capsules (UDCA 250mg & Silymarin 140mg) versus UDCA alone versus Placebo among Compensated Chronic Liver Disease Patients		specialized Hospital -National Hepatology and Tropical Research Institute (NHTMRI)	Suspended (Recruitment suspension) 26-11-2024		Ursofalk® capsules
76-	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 pelviabdominal infections and following IV antibiotics in postoperative period, for pelvi-abdominal	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)

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Color	Orange	Medical Device
Indicator	Gray	Innovative
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				surgeries or acute conditions					
77-	15/5/2023	Sub- Thromb- 001	Sponsor: Minapharm	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	IV	1- Department of Orthopedics and Trauma Surgery, El-Hadra University Hospital	Withdrawn 28-8-2023	prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations	Innovative Thrombex (recombinant Hirudin)

Color Indicator Green Biological
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CV/EG/3	Nerhadou	Multicentre, Open-		General Internal	10-3-2024	Hypertension	
9/IV	Internatio-	label, Single-arm		Medicine, Beni-			Nerkardou
	nal	Interventional Study		Suef University	Recruiting		(Bisoprolol)
		of Bisoprolol		Hospital			Oral dispersible
	CRO:	(Nerkardou)		2- Department of			film
	Genuine	(Between Low Dose		Cardiology and			
	research	and High Dose) 5		vascular			
	center	and 10 mg ODF		medicine,			
		Treatment In		Fayoum			
		Egyptian Patients		University			
		with Essential		Hospital			
		Hypertension					
	9/IV	9/IV International CRO: Genuine research	9/IV International Study of Bisoprolol CRO: (Nerkardou) Genuine research and High Dose) 5 center and 10 mg ODF Treatment In Egyptian Patients with Essential	9/IV International Study of Bisoprolol (Nerkardou) Genuine (Between Low Dose research and High Dose) 5 center and 10 mg ODF Treatment In Egyptian Patients with Essential	9/IV Internatio- nal Interventional Study of Bisoprolol CRO: (Nerkardou) Genuine (Between Low Dose research and High Dose) 5 center and 10 mg ODF Treatment In Egyptian Patients with Essential Medicine, Beni- Suef University Hospital Cardiology and vascular medicine, Fayoum University Hospital	9/IV International Study of Bisoprolol (Nerkardou) (Between Low Dose research and 10 mg ODF Treatment In Egyptian Patients with Essential Suef University Hospital Suef University Hospital 2- Department of Cardiology and vascular medicine, Fayoum University Hospital	9/IV International Study of Bisoprolol (Nerkardou) (Senuine research and 10 mg ODF Treatment In Egyptian Patients with Essential Suef University Suef University Hospital Suef University Suef University Hospital Recruiting Recruiting Recruiting Suef University Hospital

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