Bio-Inn



جمهورية مصر العربية هيئة الدواء المصرية الادارة المركزية للمستحضرات الحيوية و المبتكرة والدراسات الاكلينيكية 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clinical trials will be conducted in Egypt"	Status/Date: - Approved - Recruiting - Recruitment completion - Completed - Withdrawn - Suspended - Terminated	Conditions / Therapeutic Area	Interventions Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)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	Approved 26/03/2019 Completed 03/11/2021	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

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2	27\12\2019	M16 000	Spongow	A Multicontor	Ш	5- National hepatology and tropical medicine institute 6- Faculty of medicine, Zagazig university	Approved	Crohn's	(Piological)
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	III	1- Two sites at Faculty of Medicine, CRC, Alexandria University	Approved 26/03/2019 Recruitment completion	Crohn's disease	(Biological) Risankizumab

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

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3-	28\02\2019	M16-066	Sponsor: Abbvie	completed M15- 989 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	III	1- Faculty of medicine, CRC, Alexandria University 2- CRC, Alexandria University 3- Air Force Specialized Hospital Research 4- National Liver Institute, Menoufia	Approved 10/06/2019 Recruitment completion	Ulcerative Colitis	(Biological) Risankizumab
4-	28\02\2019	M16-067	Sponsor: Abbvie	Multicenter randomized double-blind placebo-controlled induction study to evaluate the efficacy and safety of Risankizumab in subjects with	III	University 1- CRC, faculty of medicine, Alexandria University 2- National Liver Institute, Menoufia University	Approved 10/06/2019 Completed: 30/11/2023	Active ulcerative colitis.	(Biological) Risankizumab

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

Bio-Inn



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				moderately to severely active ulcerative colitis.		3- Air Force Specialized Hospital 4- Faculty of Medicine, CRC, Alexandria University			
5-	07/05/2019	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	Ш	1- Faculty of medicine, Alexandria university 2- Faculty of medicine, Ain Shams University	Withdrawn 31/08/2020	Chronic spontaneous Urticaria	(Biological) Ligelizumab

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

Bio-Inn



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6-	18/09/2019	ARTEMI S-DM	Sponsor: SANOVI	A multicenter, multinational,	IV	1- Faculty of medicine,	Approved 09/02/2020	Type 2 diabetes	(Biological)
		"LPS1539	Brit (O) I	prospective,		Alexandria	07/02/2020	mellitus	Insulin glargine
		6"		interventional,		university			"Toujeo"
				single-arm, Phase		2- CRC,	Withdrawn		
				IV study evaluating		Alexandria			
				the clinical efficacy		university			
				and safety of 26		3- GOTHI			
				weeks of treatment		4- Faculty of			
				with insulin		medicine,			
				glargine 300 U/mL		Menoufia			
				(Gla-300) in		university			
				patients with Type		5- Faculty of			
				2 diabetes mellitus		medicine, Ain			
				uncontrolled on		Shams			
				basal insulin		university			
7-	18/11/2019	STAND	Sponsor:	A phase II,	II	1- Abu El Resh	Approved	Sickle cell	(Biological)
			Novartis	multicenter,		Children	05/05/2020	anemia	
				randomized, open		Hospital			Crizanlizumab
				label, two arm					
				study comparing			Withdrawn		
				the effect of			03/08/2021		
				crizanlizumab+					
				SOC alone on renal					
				function in sickle					
				cell disease					
				patients ≥16 years					

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

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8-	24/03/2020	STEAD FAST	Sponsor: Novartis	with chronic kidney disease due to sickle cell nephropathy 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	III	1- Faculty of medicine, Alexandria university 2- Faculty of medicine, Ain Shams university	Approved 20/02/2020 Withdrawn 03/08/2021	Sickle cell anemia	(Biological) Crizanlizumab
				adult sickle cell disease patients with vaso- occlusive crisis					
9-	30/03/2020	WA40404	Sponsor: Roche	A Phase III b Multicenter, Randomized, double-blind, Placebo-controlled	IIIb	1- Sayed Galal Hospital 2- Faculty of medicine,	Approved 23/08/2020 Withdrawn 25/08/2021	Primary progressive multiple sclerosis	(Biological) Ocrelizumab

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

Bio-Inn



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				study to evaluate the efficacy and safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis		Alexandria university 3- CRC, MASRI, Ain Shams University			
10-	14\09\2020	1368-0025	Sponsor: Boehringe r Ingelheim	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 18/05/2021 Withdrawn 31/10/2021	Generalized pustular psoriasis	(Biological) Spesolimab
11-	21/09/2020	05-Gam- COVID- Vac-2020	Sponsor: Russian Direct Investmen t 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	III	1- National liver institute, Menoufia university 2- CRC, faculty of medicine, Alexandria university 3- CRC, MASRI, Ain	Withdrawn 12/06/2022	COVID-19 prophylaxis	(Biological) Russian Gam- COVID-Vac Combine vector vaccine

	Green	Biological
	Blue	Pharmaceutical
Color	Orange	Medical Device
Indicator	Gray	Innovative
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12-	22/09/2020	CNBG202 0003SQ	Sponsor: China National Biotec Group company limited Wuhan institute of biological products Co. Ltd Beijin institute of biological	prophylactic treatment for SARS-COV-2 infection in Egypt 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	Shams University 1- Vacsera Health care facility 2- Ktameya medical center	Approved 28/03/2022 Completed 31/07/2022	COVID-19 Prophylaxis	(Biological) Inactivated SARS- COV-1 Vaccine
			products Co.Ltd						
13-	13/04/2021	D910DC0 0001 (Emerald- 2)	Sponsor: AstraZene ca	A phase 3 randomized double blind placebo controlled multicentre study	III	1- CRC, Faculty of medicine, Alexandria University hospital	Approved 12/12/2021	Hepatocellul ar carcinoma patients at high risk of recurrence	(Biological) Durvalumab\ Bevacizumab

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





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			CRO: IQVIA	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		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	after curative hepatic resection or ablation	
14-	19/05/2021	01- Sputnik- Light- 2021	Sponsor: Human vaccine LLC (Global), Russian ministry of healthcare	A phase III, randomized, double-blind, placebo-controlled international multi- site clinical trial in parallel assignment to evaluate efficacy,	III	1- National hepatology and tropical medicine center 2- Katemeya medical center	Approved 24/08/2021 Completion of study visit 31/08/2022	COVID-19 Prophylaxis	(Biological) Sputnik Light vector vaccine

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



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			Gamalya (Local) CRO: PDC	immunogenicity and safety of the Sputnik Light vector vaccine in adults in the SARS-Cov-2 infection prophylactic treatment					
15-	25/05/2021	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	III	1- Faculty of medicine, Kasr Al-Ainy hospital 2- Shefaa Al-Orman hospital 3- Baheya Hospital	Approved 05/12/2021 Withdrawn 19/12/2022	HER2- positive and PD-L1- positive locally advanced or metastatic breast cancer	(Biological) Trastuzumab Emtansine/ Atezolizumab

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herhal

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				Trastuzumab + Atezolizumab and Taxane- based therapy					
16-	27/05/2021	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	III	1-CRC, Faculty of medicine, Alexandrian university	Withdrawn 03/11/2021	Active ankylosing spondylitis	(Biological) Secukinumab
17-	05/08/2021	TG2101V 01	Sponsor:	A Global, Multi- Center, Randomized,	III	1-National Hepatology and Tropical	Withdrawn 16/01/2022	COVID-19 Prophylaxis	(Biological)

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



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			Livzon mabpharm Inc.	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",		Medicine Research Institute (NHTMRI)			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 Lenvatinib or sorafenib alone in hepatocellular carcinoma previously treated with Atezolizumab and Bevacizumab	III	1- Air force specialized hospital	Approved 02/02/2022 Recruitment completion	Hepatocellul ar carcinoma	(Biological) Atezolizumab/ Lenvatinib/ Sorafenib

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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19-	02/09/2021	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	1- National research center	Approved 09/11/2021 Suspended 09/12/2021	Covid-19 Prophylaxis	(Biological) Inactivated SARS-CoV-2 Vaccine
20-	17/01/2022	SPHINX- EGYPT SPHINX2 2122020	Sponsor: - EVA PHARMA - VSVRI - supreme council of university hospitals - Ministry of higher education and scientific research CRO: Dataclin	Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2 Infection (COVID- 19)	I	1- Al-Manial specialized university Hospital, Cairo university hospitals	Approved 03/02/2022 Database lock 26/09/2023	Covid-19 Prophylaxis	(Biological) EgyVax

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

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21-	04/11/2021	GBT2104-	Sponsor:	A randomized	III	1- Faculty of	Approved	sickle cell	(Biological)
		131	Global	double blinded		medicine,	14/06/2022	disease	
			blood	placebo controlled		Mansoura		patients with	Inclacumab
			therapeuti	multicentre study		University		Vaso-	
			cs Inc. \	to access the safety		2- Faculty of		occlusive	
			Pfizer	and efficacy of		medicine,	Completed:	crisis	
				Inclacumab in		Zagazig	30/05/2025		
			CRO:	participants with		University			
			MCT	sickle cell disease		3- MASRI-			
				experiencing Vaso-		CRC, Faculty of			
				occlusive crisis		medicine, Ain			
						Shams			
						University			
						hospital			
						4- CRC,			
						Alexandria			
						University			
						5- Pediatric			
						hematology			
						department,			
						Alexandria			
						University			
						6- CRC, faculty			
						of medicine,			
						Cairo			
						University, Abo			

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



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	0.4/01/2022	CDT2104	a			El-Resh Hospital 7- CRC, Cairo University 8- Hematology department, Cairo University hospital		0: 11 11	
22-	04/01/2022	GBT2104- 132	Sponsor: 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)	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	Approved 14/06/2022 Withdrawn 29/06/2023	Sickle cell disease patients with Vaso- occlusive crisis	(Biological) Inclacumab

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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						University hospital 5- Hematology department, Alexandria University hospital 6- Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University			
23-	28/11/2021	GBT2104-	Sponsor:	An Open-label	III	8- Cairo University, Hematology department. 1- Faculty of	Approved	sickle cell	
	20/11/2021	133	Global blood therapeuti cs Inc.\ Pfizer CRO: MCT	Extension Study to Evaluate the Long- term Safety of Inclacumab Administered to Participants with Sickle Cell Disease Who Have Participated in an		medicine, Mansoura University 2- Faculty of medicine, Zagazig University 3- MASRI, CRC, Ain	14/06/2022 Withdrawn 17/12/2023	disease	(Biological) Inclacumab/ Placebo

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

QF: Bio Inn.231.01

Herbal

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	Inclacumab Clinical Trial	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 CPG C		
		7- CRC, Cairo		
		University		
		8- Cairo		
		University,		
		Hematology		
		department.		

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

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24-	08\06\2022	Consonan ce- MN39159	Sponsor: F. HOFFMA NN-LA ROCHE LTD CRO: Roche Egypt LLC & IQVIA (for monitorin g 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	1- CRC, Faculty of Medicine, Alexandria university, CRC 2- MASRI- CRC, faculty of medicine, Ain Shams university hospital	Approved 20/09/2022 Recruitment completion	Progressive multiple sclerosis	(Biological) Ocrelizumab
25-	09\02\2022	20200404 (IMBCA M	Sponsor: Institute of Medical Biology Chinese Academy of Medical Sciences	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 24/02/2022	Covid-19 Prophylaxis	(Biological) Inactivated SARS- COV-2 vaccine

Color	
Indicator	

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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			CRO:						
			PDC						
26-	10/05/2022	TRISTAR	Sponsor:	The TRISTARDS	IIb/III	1- National	Withdrawn	Respiratory	(Biological)
		DS-	Boehringe	trial -ThRombolys		Hepatology and	20/07/2022	distress	
		0135-0347	r	is Therapy for		Tropical		syndrome	Alteplase
			Ingelheim	ARDS A Phase		Medicine		(ARDS)	
				IIb/III		Research		triggered by	
			CRO:	operationally		Institute		COVID-19	
			MCT	seamless, open-		2- Abbasia			
				label, randomized,		Fever Hospital			
				sequential, parallel-		3- Imbaba Fever			
				group adaptive		Hospital			
				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					
				syndrome (ARDS)					

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

Bio-Inn



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				triggered by					
				COVID-19.					
27-	14/08/2022	CAIN457	Sponsor:	A randomized,	III	1- CRC, Faculty	Approved	Treatments	(Biological)
		A2310	Novartis	double-blind,		of Medicine,	04/12/2022	of severe	
				placebo- and active		Alexandria		chronic	Secukinumab
			CRO:	controlled		university		plaque	
			MCT	multicenter trial to		hospital		psoriasis	
				demonstrate		2- Dermatology	Early terminated		
				efficacy of		department,	by sponsor		
				subcutaneous		faculty of	31/03/2023		
				Secukinumab		Medicine, Ain			
				compared to		Shams			
				placebo and		University			
				etanercept (in a		hospital			
				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					

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



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28-		SCTV01E	Sponsor:	A randomized	III	1- Katemya	Withdrawn	COVID-19	(Biological)
	08/11/2022	-MRCT-1	Sinocellte	double blind		Medical Center	14/01/2023	prophylaxis	` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `
			ch	positive controlled		2- Egyptian		1 1 2	SCTV 01E
				phase III clinical		Liver research			(a covid-19
			CRO:	trial to evaluate the		institute and			alpha/beta/delta/
			PDC	efficacy and safety		hospital			omicron variants s-
				of SCTV01E (a		•			trimmer vaccine)
				covid-					(Biological)
				19alpha/beta/delta/					_
				omicron variants s-					
				trimmer vaccine) in					
				population					
				previously					
				unvaccinated with					
				COVID-19 vaccine					
				and aged ≥18					
29-	06/06/2023	FUZION	Sponsor:	A Phase 3,	III	1- National	Approved	Fistulizing	Guselkumab
		CNTO195	Janssen	Randomized,		Hepatology	13/08/2023	perianal	
		9CRD		Placebo-controlled,		Tropical		Crohn's	(Biological)
			CRO:	Parallel-group,		Medicine	Recruiting	disease	
			MCT	Multicenter Study		Research			
				to Evaluate the		Institute			
				Efficacy and Safety		2- CRC, faculty			
				of Guselkumab in		of medicine			
				Participants with		Alexandria			
				Fistulizing,		university			
				Perianal Crohn's					

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herhal

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				Disease "FUZION		hospital, (two			
				CD"		sites)			
						3- Department			
						of internal			
						medicine, El			
						Kasr Al Aini,			
						Cairo University			
						4- MASRI			
						CRC, faculty of			
						medicine, Ain			
						Shams			
						University			
						Hospital			
30-	14/05/2023	MP-	Sponsor:	A Phase I,	I	1- CRS clinical	Approved	Inflammatory	Adessia
		ADA1-01	Minaphar	randomized,		research	10/08/2023	disease	
			m	double-blind, 2-		services, Berlin		(Biosimilar	(Biological)
				arm, parallel group		GmbH		to Humira)	
			CRO:	trial to compare		2- CRS clinical	Completed		
			CRS	pharmacokinetics		research			
			Clinical	of Adessia with		services,			
			Research	EU-authorized		Mannheim			
			Services	Humira in healthy		GmbH			
			Berlin	male and female					
			GmbH	participants"					

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

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31-	04/05/2023	MOM-	Sponsor:	Efficacy and Safety	II/III	1- National	Approved	Warm	M281
31-	0-7/03/2023	M281-006	Janssen	of M281 in Adults	11/111	Cancer Institute,	19/07/2023	Autoimmune	141201
		141201 000	Janssen	with Warm		Cairo university	17/07/2023	Hemolytic	(Biological)
			CRO:	Autoimmune		2- Oncology	Early Terminated	Anemia	(Diological)
			MCT	Hemolytic Anemia:		center, Mansoura	<u> </u>	Ancima	
			MC1	A Multicenter,		University	21/02/2025		
				Randomized,		Hospital	21/02/2023		
				Double-blind,		3- Department of			
				Placebo-controlled		internal			
				Study with a Long-		medicine, Al			
				term Open-label		Kasr al Eini,			
				Extension"		Cairo university			
				Extension		4- Naser institute			
						hospital for			
						research and			
						treatment			
						5- CRC, faculty			
						of medicine,			
						Alexandria			
						university			
						•			
						Hospital			
						6- CRC, faculty			
						of medicine, Ain			
						shams university			
						Hospital			

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

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32-	shift to amendment submission 26\12\2023	EMERAL D-3) D910VC0 0001	Sponsor: AstraZene ca CRO: IQVIA	A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)		1- Air Force specialized hospital 2- Oncology department, Faculty of medicine, Alex University 3- Egyptian liver Hospital National Hepatology and Tropical Medicine Research Institute (NHTMRI) 4- Shifa El orman Hospital	Approved 08/02/2024 Recruiting	Locoregional Hepatocellular Carcinoma	(Biological) Durvalumab / Tremelimumab/ Lenvatinib /TACF
33-	not submitted officially	CERE- CAP	Investigat or- initiated	Efficacy of Cerebrolysin as an adjuvant therapy following mechanical thrombectomy in	III	1- Neurology and psychiatry department, Ain Shams University Hospital	Terminated (by EDA) (15/01/2024)	occlusion stroke	(Biological) CEREBROLYSI N solution for IM or IV injection/ concentrate for

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

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				patients with large vessels occlusion stroke					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	1- Faculty of Medicine, Alexandria University 2- Faculty of Medicine, Cairo University	Approved: 22/04/2024 Withdrawn: 25\12\2024	Her-2 positive breast cancer	Biological BCD-178
35-	08/01/2024	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 (AP-0102)	IIb	1- Ain Shams University Medical Research Institute (MASRI)	Conditional Approved 13/06/2024 Final Approval 31/10/2024 Withdrawn: 16/01/2025	Hemophilia A or Moderately Severe to Severe Hemophilia B	Biological SerpinPC 102

	Green	Biological
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Color	Orange	Medical Device
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36-	08/01/2024	SerpinPC1 03	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)	IIb	1- Ain Shams University Medical Research Institute (MASRI)	Conditional Approved 13/06/2024 Final Approval 31/10/2024 Withdrawn: 16/01/2025	Hemophilia B with Inhibitors	Biological Serpin PC 103
37-	08/02/2024	D9185C00 001" TILIA'	Sponsor: AstraZenc a CRO: IQVIA	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: 04/08/2024 Withdrawn: 30/01/2025	Patients hospitalized for viral lung infection	Biological Tozoralimab

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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38-	16/01/2025	GA45329- Ametrine 1	Sponsor: Roche	A Phase III, Multicenter, Double-Blind,	III	1- Clinical Research Center, Internal	Approved: 10/03/2025	Patients with Moderately to Severely	Biological
				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		Medicine Faculty of Medicine, Alexandria University	Withdrawn: 10/09/2025	Active Ulcerative Colitis	RO7790121
39-	16/01/2025	GA45330- Ametrine 2	Sponsor: Roche	Ulcerative Colitis 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	III	1- Clinical Research Center, Internal Medicine Faculty of Medicine, Alexandria University	Approved: 10/03/2025 Withdrawn: 10/09/2025	Patients with Moderately to Severely Active Ulcerative Colitis	Biological RO7790121

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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				Severely Active Ulcerative Colitis					
40-	11\05\2025	GA45331	Sponsor: Roche	A Phase III Multicenter Double Blind 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 Crohn's disease	III	1-Clinical Research Center, Faculty of Medicine, Alexandria University Hospital 2-Air Force Specialized Hospital 3-National Liver Institute, Menoufya University	Approved: 01\06\2025	Crohn's Disease	Biological RO7790121
41-	17/12/2020	CEGA230 B2404	Sponsor: Novartis CRO: MCT	A Phase IV Multicenter Open Label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of	IV	1-Cairo University, Al Mounira Children Hospital, Pediatric Hepatology Unit.	Approved 12/04/2021 Recruiting	Fascioliasis	(Pharmaceutical) Triclabandazole (Egaten)

Color Indicator	

Green	Biological
Blue	Pharmaceutical
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Gray	Innovative
Red	Herbal

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				Egaten (Triclabandazole) in Patients 6 Years of Age or Older with Fascioliasis (Egaten)		2-Alexandria University, Faculty of Medicine, Clinical Research Center.			
42-	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 Patients with Hormone Receptor- Positive/HER2- Negative Inoperable Locally Advanced or Metastatic Breast	II	1-Ain Shams University, Faculty of Medicine, Clinical Research Center, (MASRI – CRC) 2-Baheya Hospital Research Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center	Approved 14/10/2021 Completed 08/01/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy

Color Indicator	

Green	Biological
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				Cancer - RIGHT					
				Choice Study					
43-	24/10/2021	M14-430	Sponsor:	A Multicenter,	III	1-Air Force	Approved	Chron's	(Pharmaceutical)
43	21/10/2021	1411 130	Abbvie	Randomized,	111	Specialized	07/07/2022	Disease	(1 marmaceaticar)
			7100110	Double-Blind,		Hospital	07/07/2022	Discuse	Upadacitinib/
				Placebo-Controlled		2-National Liver	Recruitment		matching placebo
				Maintenance and		Institute	Completion		matering pracess
				Long-Term		Menoufiya	Completion		
				Extension Study of		University			
				the Efficacy and		3-Alexandria			
				Safety of		University,			
				Upadacitinib		Faculty of			
				(ABT-494) in		Medicine,			
				Subjects with		Clinical Research			
				Crohn's Disease		Center.			
				Who Completed		4-Ain Shams			
				the Studies M14-		University,			
				431 or M14-433		Faculty of			
						Medicine,			
						Clinical Research			
						Center (MASRI-			
						CRC).			
44-	26/10/2021	BO40336	Sponsor:	A Phase III, Open-	III	1- Cairo	Approved	Lung Cancer	(Pharmaceutical)
		ALINA	Roche	Label, Randomized		University, Kasr	16/03/2022	_	
				Study to Evaluate		Al Eini, Center of			
				the Efficacy and		Radiation			

	Green	Biological
Color	Blue	Pharmaceutical
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Indicator	Gray	Innovative
	Red	Herbal



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				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		Oncology and Nuclear Medicine.	Recruitment Completion		Alectinib / Platinum based Chemotherapy
45-	12/12/2021	Cl_Tr_17 122019 MIRACL E-ALA	Sponsor: EVA Pharma CRO: MARC	Lung Cancer 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- Alexandria University Hospital, Diabetes, Metabolism, and Lipidology Unit, Department of Internal Medicine.	Approved 12/10/2022 Completed 11/12/2024	Treatment of Symptomatic Diabetic Polyneuropat hy	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo

Color **Indicator**

Green	Biological
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Red	Herbal

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				Treatment of Patients with Symptomatic Diabetic Polyneuropathy in Egypt		2- Ain Shams University Hospital 3- Menoufiya University Hospital 4- Mansoura University, Intrinsic Specialized Hospital. 5- Beni-Suef University Hospital, Diabetes and Endocrinology			
46-	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	III	Unit. 1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Air Force Specialized Hospital. 3-National Hepatology and	Approved 18/01/2022 Completed 16/11/2022	Prophylaxis of COVID- 19	(Pharmaceutical) Molnupiravir/ matching placebo

Color
Indicator

Green	Biological
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Orange	Medical Device
Gray	Innovative
Red	Herbal

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				(Laboratory Confirmed SARS- COV 2 Infection with Symptoms) in Adults.		Tropical Medicine Research Institute. 4-Imbaba Fever Hospital. 5-National Center for Allergies and Chest Imbaba			
47-	30/03/2022	GBT440- 032	Sponsor: GBT (Subsidiar y 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,	Approved 31/07/2022 IMP Dosing Pause 02/05/2024 Early Termination by the sponsor 29/09/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo

Color
Indicator

Green	Biological
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Orange	Medical Device
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						Department of Pediatrics.			
48-	18/04/2022	GBT440- 034	Sponsor: GBT (Subsidiar y 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	III	1-Cairo University, Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center 4-Zagazig University Hospital, Department of Pediatrics.	Approved 02/08/2022 Early Termination by the sponsor 30/09/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor
49-	17/05/2022	F901318/0 032	Sponsor: F2G CRO: IQVIA	Open Label Single Arm Phase IIb Study of F901318 as Treatment of Invasive Fungal Infections Due to	IIb	1-Mansoura University Oncology center 2-Alexandria University,	Terminated (By Sponsor) 24/07/2022	Invasive Fungal Infection	(Pharmaceutical) Olorofim

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Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

				Lomentospora Prolificans, Seedosporium Spp., Aspengillus Spp., & other Resistant Fungi in Patients Lacking Suitable Alternative		Clinical Research Center 3-Nasser Institute 4-Ain Shams University Clinical Research Center, (MASRI – CRC) 5-Air Force specialized Hospital 6-National			
50	12/06/2022	CI CVN 1	Connection	A 2-2 F- 4	HI/IX/	University Kasr Al-Eini, Hospital	A	CTEMIAL.	(Dla massacia I)
50-	12/06/2022	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	III/IV	1-Mansoura University Hospital 2-Suez Canal University Hospital	Approved 24/07/2022 Completed 01/08/2024	STEMI/Non- STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo

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Color Indicator	Blue	Pharmaceutical
	Orange	Medical Device
	Gray	Innovative
	Red	Herbal

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Biological

Innovative Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

51-	15/06/2022	20140106	Sponsor: Onyx Pharmace uticals (Subsidiar y of Amgen) CRO:	GY Stent Registry Organization to Assess Strategies for Ischemic Syndromes 9 Phase 1b/2 Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic	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 23/08/2022 Withdrawn 19/06/2023	Relapsed or Refractory Acute Lymphoplast ic Leukemia	(Pharmaceutical) Carfilzomib
52-	18/07/2022	AG348-C- 020	IQVIA Sponsor: Agios CRO: MCT	Leukemia A Phase 2/3, Double-Blind, Randomized, Placebo- Controlled, Multicenter Study	II/III	1-Alexandria University Clinical Research Center	Approved 27/09/2022 Withdrawn 21/08/2023	Sickle Cell Disease	(Pharmaceutical) Mitapivat / matching placebo

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

53-	26/07/2022	F901318/0 041	Sponsor: F2G CRO: IQVIA	to Evaluate the Efficacy and Safety of Mitapivat in Subjects with Sickle Cell Disease A Phase III, Adjudicator-Blinded, Randomised Study to Evaluate the Efficacy and Safety	III	2-Zagazig University Hospital 3-Cairo University Hospital 4-Mansoura University Hospital 5-Ain Shams University Clinical Research Center (MASRI-CRC) 1-Mansoura University Oncology Center 2-Alexandria University	Approved 11/10/2022	Invasive Fungal Disease caused by Aspergillus species	(Pharmaceutical) Olorofim / Ambisome
		041		Blinded,		Oncology	11/10/2022	Disease	
				•				•	Amoisome
			10,111						
				of Treatment with		Clinical		or	
				Olorofim Versus		Research Center			
				Treatment with		3-Air Force			
				Ambisome®		specialized			
				Followed by		Hospital			
				Standard of Care		4-Ain Shams			
				(SOC) in Patients		University,			

Color
Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

				with Invasive		Clinical			
				Fungal Disease		Research Center			
				(IFD) Caused by		(MASRI-CRC)			
				Aspergillus Species		5-Zagazig			
						University			
						Hospital			
						6-National			
						Cancer Institute			
						7-Cairo			
						University Kasr			
						Al Eini Hospital			
						8-Nasser			
						Institute for			
						Research and			
						Treatment			
54-	27/07/2022	APD334-	Sponsor:	A Multicenter	III	1-Alexandria	Approved	Moderately	(Pharmaceutical)
		202	Arena	Randomized		University	23/08/2022	to Severe	
			Pharmace	Double Blinded		Clinical		Active	Etrasimod /
			uticals	Parallel Group		Research Center	Recruitment	Crohn's	matching placebo
			(Subsidiar	Study to Assess the		2-Air Force	Completion	Disease	
			y of	Efficacy and Safety		Specialized			
			Pfizer)	of Oral Etrasimod		Hospital	Early		
				as Induction and		3-National Liver	Terminated by		
				Maintenance		Institute	the sponsor		
				Therapy for		4-National	20/03/2025		
				Moderately to		Hepatology and			
				Severe Active		Tropical			

Color **Indicator**

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

				Crohn's Disease (Etrasimod)		Medicine Research Institute (NHTMRI) 5-Cairo University Kasr Al-Eini Hospital 6-Egyptian Liver Research Institute and Hospital 7-Ain Shams University Hospital 8-Theodor Bilharz Research			
55-	07/08/2022	EFC17215 LEAP-2- MONO	Sponsor: Sanofi	A Phase 3, Multicenter, Multinational Randomized Double-Blind Double-Dummy, Active Comparator Study to Evaluate the Efficacy and	III	Institute 1-Alexandria University Hospital Clinical Research Center	Approved 24/10/2022	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme

Color **Indicator**

Green Biological Pharmaceutical Blue **Orange Medical Device** Innovative Gray Red Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

56-	15/08/2022	AG348-C- 017	Sponsor: Agios	Safety of Venglustat in Adult and Pediatric Patients with Gaucher Disease Type 3 (GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy A Phase 3, Double- blind, Randomized,	III	1-Cairo University	Approved 02/11/2022	Non- Transfusion-	(Pharmaceutical)
			CRO: MCT	Placebo- Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Non— Transfusion- Dependent Alpha- or Beta- Thalassemia (ENERGIZE)		Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Withdrawn 26/06/2023	Dependent Alpha or Beta Thalassemia	Mitapivat / matching placebo

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

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57-	15/08/2022	AG348-C-	Sponsor:	A Phase 3, Double-	III	1-Cairo	Approved	Transfusion-	(Pharmaceutical)
		018	Agios	blind, Randomized,		University	02/11/2022	Dependent	
				Placebo-		Hospital		Alpha or	Mitapivat /
			CRO:	Controlled,			Withdrawn	Beta	matching placebo
			MCT	Multicenter Study		2-Ain Shams	26/06/2023	Thalassemia	
				Evaluating the		University			
				Efficacy and Safety		Clinical			
				of Mitapivat in		Research Center			
				Subjects with		MASRI-CRC			
				Transfusion-					
				Dependent Alpha-					
				or Beta-					
				Thalassemia					
				(ENERGIZE-T)					
58-	29/08/2022	4202-	Sponsor:	An Adaptive,	III	1- Alexandria	Approved	Sickle Cell	(Pharmaceutical)
		HEM-301	Forma	Randomized,		University	11/12/2022	Disease	
			Therapeuti	Placebo-		Clinical			Etavopivat /
			cs	Controlled,		Research Center	Recruitment		matching placebo
				Double-blind,		2-Zagazig	Completion		
			CRO:	Multi-center Study		University			
			MCT	of Oral Etavopivat,		Hospital			
				a Pyruvate Kinase		3-Cairo			
				Activator in		University			
				Patients with		Hospital			
				Sickle Cell Disease		4-Ain Shams			
						University			
						Clinical			

Color
Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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GA of Clinical Trials Protocols & Studies Follow up Administration

						Research Center			
						(MASRI-CRC)			
59-	29/09/2022	GO42784	Sponsor:	A Phase III,	III	1-Alexandria	Approved	Estrogen	(Pharmaceutical)
39-	29/09/2022		-	· · · · · · · · · · · · · · · · · · ·	111				(Filatiliaceutical)
		LIDERA	Roche	Randomized,		University	04/12/2022	Receptor-Po	C: 1 /
			CDO	Open-Label,		Hospital	D '4 4	sitive, Her2-	Giredestrant /
			CRO:	Multicenter Study		2-Medical	Recruitment	Negative	Physician Choice
			MCT	Evaluating the		Research	Completion	Early Breast	of Adjuvant
				Efficacy and Safety		Institute,		Cancer	Endocrine
				of Adjuvant		Alexandria			Monotherapy
				Giredestrant		University			
				Compared with		3-Mansoura			
				Physician's Choice		University			
				of Adjuvant		Hospital			
				Endocrine		4-Cairo			
				Monotherapy in		University Kasr			
				Patients with		Al- Ainy			
				Estrogen		Hospital			
				Receptor-Positive,		5-Ain Shams			
				Her2-Negative		University			
				Early Breast		Demerdash			
				Cancer		Hospital			
						6- Dar El Salam			
						Cancer Hospital			
						7- Sohag			
						Oncology			
						Center			

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

60-	16/11/2022	(ACTIV- 2D/A5407	Sponsor: Shionogi CRO:	A Phase 3, Multicenter, Randomized, Double-Blind, 24-	III	1-National Hepatology and Tropical Medicine	Approved 31/01/2023 Withdrawn	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo
			IQVIA	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	26/09/2023		matering praceoo
61-	28/11/2022	RBSC216	Sponsor:	A Phase 2a	IIa	Hospital 1-Cairo	Approved	Sickle Cell	(Pharmaceutical)
		1	Salix	Randomized,		University Abu	05/02/2023	Disease	

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



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			pharmace uticals CRO: IQVIA	Double-Blind, Placebo-Controlled Study to Characterize the Pharmacokinetics and Pharmacodynamics of Rifaximin Novel Formulations in Patients with Sickle Cell Disease		El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Zagazig University Hospital 4-Cairo University Hospital 5-Alexandria University Clinical	Withdrawn 06/11/2023		Rifaximin / matching placebo
62-	22/01/2023	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	III	Research Center 1- National Hepatology and Tropical Medicine Research Institute	Approved: 15/10/2023 Withdrawn 07/04/2024	COVID-19	(Pharmaceutical) Bemnifosbuvir/mat ching Placebo

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

				Outpatients with COVID-19					
63-	13/02/2023	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 10/05/2023 Recruitment Completion	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

						8-Assuit University Hospital			
64-	13/02/2023	GBT440- 038	Sponsor: GBT (Subsidiar y 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	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 30/03/2023 IMP Dosing Pause 02/05/2024 Early Terminated by the Sponsor 26/09/2024	Sickle Cell Disease	(Pharmaceutical) Voxelotor
65-	01/03/2023	GN41851 FENHANC E	Sponsor: Roche	A Phase III Multicentre, Randomized, Double-Blind, Double-Dummy, Parallel-Group	III	1-Alexandria University- Clinical Research Center	Approved 26/4/2023 Withdrawn 11/01/2024	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

				Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Teriflunomide In Adult Patients with Relapsing Multiple Sclerosis.					
66-	06/03/2023	1305-0023 (FIBRONE ER –ILD	Sponsor: Boehringe 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)	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 01/06/2023 Withdrawn 17/01/2024	Progressive Fibrosing Interstitial lung diseases (PF- ILDs)	(Pharmaceutical) BI 1015550 / matching placebo
67-	06/03/2023	1305-0014	Sponsor: Boehringe	A Double Blind, Randomized,	III	1- Ain Shams University	Approved 01/06/2023	Idiopathic Pulmonary	(Pharmaceutical)

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

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GA of Clinical Trials Protocols & Studies Follow up Administration

		(FIBRON	r	Placebo-Controlled		Clinical		Fibrosis	BI 1015550 /
		EER –	Ingelheim	Trial Evaluating		Research Center	Withdrawn	(IPF)	matching placebo
		IPF)		the Efficacy and		(MASRI-CRC)	08/01/2024		
			CRO:	Safety of BI		2- Alexandria			
			IQVIA	1015550 Over At		University			
				Least 52 Weeks in		Clinical			
				Patients with		Research Center			
				Idiopathic		3- Air Force			
				Pulmonary Fibrosis		Specialized			
				(IPF)		Hospital			
						4- Cairo			
						University, Kasr			
						Al Ainy			
						Hospital			
68-	16/03/2023	4202-	Sponsor:	A Phase 2 Open-	II	1- Cairo	Approved	Thalassemia	(Pharmaceutical)
		HEM-201	Forma	Label Study to		University, Abu	01/06/2023	or Sickle Cell	
			Therapeuti	Evaluate Safety		El-Rich		Disease	Etavopivat
			cs	and Clinical		Children	Recruitment		
				Activity of FT-		Hospital.	Completion		
			CRO:	4202 in Patients		2-Cairo			
			MCT	with Thalassemia		University, Kasr			
				or Sickle Cell		Al Eini			
				Disease		Hospital.			
69-	15/05/2023	EFC16035	Sponsor:	A Phase 3,	III	1- Alexandria	Approved	Primary	(Pharmaceutical)
		(PERSEUS	Sanofi	Randomized,		University	10/08/2023	Progressive	
)						Multiple	

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

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				Double-Blind, Efficacy and		Clinical Research Center	Withdrawn 15/04/2024	Sclerosis	Tolebrutinib/ Matching Placebo
				Safety Study					
				Comparing					
				SAR442168 to					
				Placebo in					
				Participants with					
				Primary					
				Progressive					
				Multiple					
70	14/02/2024	WO 42571	C	Sclerosis	TIT	1 0 1	A 1	D ' 1	D1 (* 1
70-	14/03/2024	WO43571	Sponsor:	A Phase III,	III	1- Sohag	Approved	Previously	Pharmaceutical
		HereDER	Roche	Randomized,		Oncology	08/04/2024	Untreated	Giredestrant
		A		Open-Label Study		Center	D	Her2-	
				Evaluating the		2- Dar El Salam	Recruitment	Positive,	
				Efficacy and Safety of Giredestrant in		Cancer Hospital 3- National	Completion	Estrogen	
				Combination with		Cancer Institute		Receptor- Positive	
						Cancer Institute			
				Phesgo Versus				Locally- Advanced or	
				Phesgo After Induction Therapy				Metastatic	
				with Phesgo+				Breast	
				Taxane in Patients				Cancer	
				with Previously				Cancer	
				Untreated Her2-					
				Positive, Estrogen					
				Receptor-Positive					

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

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				Locally-Advanced or Metastatic Breast Cancer					
71-	22/04/2024	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 Pharmacodynamics of Roxadustat for the Treatment of Anemia in Pediatric Participants with Chronic Kidney Disease 1517-CL-1003	III	1- Cairo University Children's Hospital 2- Ain Shams University Hospital 3- Alexandria University Hospital	Approved 10/7/2024 Withdrawn 26/09/2024	Anemia in Pediatric Patients with Chronic Kidney Disease	Pharmaceutical Roxadustat
72-	05/06/2024	M23-698	Sponsor: Abbvie	A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in	III	1- Ain Shams University CRC (MASRI) 2- Air Force Specialized Hospital	Approved 07/08/2024 Withdrawn 09/04/2025	Moderate to Severe Hidradenitis Suppurativa	Pharmaceutical Upadacitinib

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

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				Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti- TNF Therapy M23-698		3- Alexandria University CRC			
73-	16/12/2024	DAY101- 002	Sponsor: Day One Biopharm aceuticals CRO: MCT	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 First- Line Systemic Therapy	III	1- 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

	Green	Biological
Color Indicator	Blue	Pharmaceutical
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74-	29/01/2025	NN7535- 7822 FLORAL	Sponsor: Forma Therapeuti cs 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	III	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)	Approved 10/04/2025 Recruiting	Adults, adolescents and children who have sickle cell disease or thalassaemia	Pharmaceutical (Etavopivat)

	Green	Biological
Color Indicator	Blue	Pharmaceutical
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						Hospital, Cairo			
						University			
75-	16/06/2025	ID-	Sponsor:	A Phase 3,	III	1- Air Force	Approved	Adult	Pharmaceutical
		064A301	Idorsia	Multicenter,		Specialized	10/08/2025	Subjects with	(Cenerimod)
		(OPUS-1)	Pharmace	Randomized,		Hospital		Moderate to	` ,
			uticals	Double-Blind,		2- Alexandria		Severe	
				Placebo-		University		Systemic	
			CRO:	Controlled,		Clinical		Lupus	
			RAY	Parallel-Group		Research Center		Erythematos	
				Study to Evaluate		3- Ain Shams		us	
				the Efficacy,		University			
				Safety, and		Clinical			
				Tolerability of		Research Center			
				Cenerimod in		(MASRI-CRC)			
				Adult Subjects					
				with Moderate-to-					
				Severe Systemic					
				Lupus					
				Erythematosus					
				(SLE) on Top of					
				Background					
				Therapy (OPUS-1)					
76-	24/07/2022	MD-004	Sponsor:	Open labelled non	III	1-Kasr Al-Aini	Approved	Hospitalized	Medical device
			Ezz	randomized self-	(pivotal)	university	28/08/2022	mechanically	(Ezvent)
			Medical	controlled study to		Hospital		ventilated	
			Industries	evaluate the safety			Suspended	patients	

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			CRO: Dataclin	and performance of Ezvent in hospitalized mechanically ventilated patients			01/01/2024 Resumed 13/01/2024 Completed 03/06/2025		
77-	15/05/2022	COAV101 B12301	Sponsor: Novartis CRO: MCT	A randomized sham controlled double –blind study to evaluate the efficacy and safety of intrathecal (IT) QAV101 in patients with later onset type 2 spinal muscular 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 02/08/2022 Early terminated (by sponsor) 18/12/2023	type 2 spinal muscular atrophy (SMA)	Innovative QAV101 (Zolgensma) (Onasemnogene abeparvovec)

	Green	Biological
	Blue	Pharmaceutical
Color	Orange	Medical Device
Indicator	Gray	Innovative
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78-	06/06/2023	Urso-003	Sponsor: Minaphar m CRO: Dataclin	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	IV	1-Clinical Research Center, Air force specialized Hospital 2-National Hepatology and Tropical Research Institute (NHTMRI)	Approved 18/09/2023 Suspended (Recruitment suspension) 26/11/2024	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/ Ursofalk® capsules
				Chronic Liver Disease Patients					
79-	06/06/2023	Cipro-001	Sponsor: Minaphar m, 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 &	IV	1- General Syrgery department, Menoufia University Hospital.	Suspended 12/09/2023	Pelvi- abdominal infections and following IV antibiotics in post- operative period, for pelvi- abdominal surgeries or	Innovative Ciprodiazole ® Tablets (Ciprofolxacin/ Metronidazole)

	Green	Biological
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		Metronidazole tablets in pelvi- abdominal infections and following IV antibiotics in post- operative period, for pelvi- abdominal surgeries or acute conditions		acute conditions	
		Interventional, Single Arm Trial for the Evaluation of subcutaneous recombinant	Surgery, El- Hadra University Hospital	(DVT) post major orthopedic operations	(recombinant Hirudin)
		Hirudin 15 mg (RB variant) in prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations			

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81-	24/10/2023	GRC/NE-	Sponsor:	A prospective,	IV	1- Department	Approved	Essential	Innovative
		CV/EG/39	Nerhadou	Multicentre, Open-		of General	10-3-2024	Hypertension	
		/IV	Internatio-	label, Single-arm		Internal			Nerkardou
			nal	Interventional		Medicine	Terminated by		(Bisoprolol)
				Study of Bisoprolol		, Beni-Suef	sponsor		Oral dispersible
			CRO:	(Nerkardou)		University	13/05/2025		film
			Genuine	(Between Low		Hospital			
			research	Dose and High		2- Department			
			center	Dose) 5 and 10 mg		of Cardiology			
				ODF Treatment in		and vascular			
				Egyptian Patients		medicine,			
				with Essential		Fayoum			
				Hypertension		University			
						Hospital			

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