

GCP Inspections Registry at EDA

SN	Study Code (Specified as per the submitted protocol)	Sponsor/CRO	Intervention(s) "Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)	Study Phase (I, II, III, or IV)	Inspected site(s)/related entities	Country: -Inside Egypt -Outside Egypt	Inspection date	Regulatory decision: -Comply -Suspended -Terminated
1.	CLEE011A3201C	Sponsor: Novartis CRO: MCT	Ribociclib (Pharmaceutical)	Phase II	Nasser Institute, Cairo	Inside Egypt	31/1/2022	Comply
2.	GBT440-032	Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI	Voxelotor (Pharmaceutical)	Phase III	Ain Shams University, Faculty of Medicine CRC (MASRI), Cairo	Inside Egypt	1/2/2022	Comply
3.	SPHINX22122020	Sponsor: Eva Pharma & Veterinary Serum & Vaccine Research Institute (VSVRI) & The Supreme Council of University Hospitals & Ministry of Higher Education and Scientific Research CRO: Dataclin	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo university hospitals	Inside Egypt	20/2/2022	Comply

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

4.	01-sputnik light-2021	Sponsor: Human Vaccine LLC CRO: PDC	Sputnik-Light: vector vaccine against the SARS-CoV-2 -induced coronavirus infection (Biological)	Phase III	Katameya Medical Center Cairo	Inside Egypt	6/3/2022	Comply
5.	MN39159	Sponsor: Roche CRO: IQIVIA	Ocrelizumab (Biological)	Phase III	CRC (MASRI), faculty of medicine, Ain Shams university hospital, Cairo	Inside Egypt	22/3/2022	Comply
6.	APD334-202	Sponsor: Arena Pharmaceuticals (Subsidiary of Pfizer) CRO: IQIVIA	Etrasimod (Pharmaceutical)	Phase II/ III	Theodor Bilharz Research Institute, Cairo	Inside Egypt	23/3/ 2022	Comply
7.	SPHINX22122020	Sponsor: Eva Pharma & Veterinary Serum & Vaccine Research Institute (VSVRI) & The Supreme Council of University Hospitals & Ministry of Higher Education and Scientific Research CRO: Dataclin	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo	Inside Egypt	10/4/2022	Comply

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

8.	GBT440-034	Sponsor: GBT (Subsidiary of Pfizer) CRO: IQVIA	Voxelotor (Pharmaceutical)	Phase III	Cairo University, Abu El Rich Hospital, Department of Pediatrics, Cairo.	Inside Egypt	13/4/2022	Comply
9.	BO40336	Sponsor: Roche CRO: NA	Adjuvant Alectinib (Pharmaceutical)	Phase III	Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine, Cairo	Inside Egypt	30/5/2022	Comply
10.	EMERALD-2	Sponsor: AstraZeneca CRO: IQIVIA	Durvalumab (Biological)	Phase III	National liver institute, Menoufia	Inside Egypt	7/6/2022	Comply
11.	MK4482-013 MOVE-Ahead	Sponsor: MSD CRO: NA	Molnupiravir (Pharmaceutical)	Phase III	National Hepatology and Tropical Medicine Research Institute (NHTMRI), Cairo	Inside Egypt	13/6/2022	Comply
12.	EMERALD-2	Sponsor: AstraZeneca CRO: IQIVIA	Durvalumab (Biological)	Phase III	National hepatology and tropical medicine institute (NHTMRI), Cairo	Inside Egypt	17/8/2022	Comply
13.	SPHINX221220 20	Sponsor: Eva Pharma & Veterinary Serum & Vaccine Research Institute (VSVRI) & The Supreme Council of University Hospitals &	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital and My lab, Cairo	Inside Egypt	24/8/2022 25/8/2022	Suspension Resumed

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

		Ministry of Higher Education and Scientific Research						
		CRO: Dataclin						
14.	01-sputnik light-2021	Sponsor: Human Vaccine LLC CRO: PDC	Sputnik-Light: vector vaccine against the SARS-CoV-2 -induced coronavirus infection (Biological)	Phase III	Katameya Medical Center, Cairo	Inside Egypt	29/8/2022	Comply
15.	EMERALD-2	Sponsor: AstraZeneca CRO: IQIVIA	Durvalumab (Biological)	Phase III	Alexandria University , CRC, Alexandria	Inside Egypt	14/9/2022	Comply
16.	GBT440-032	Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI	Voxelotor (Pharmaceutical)	Phase III	Alexandria University Faculty of Medicine, CRC, Alexandria	Inside Egypt	15/9/2022	Suspension (21/9/2022) Resuming (29/9/2023)
17.	F901318/0032	Sponsor: F2G CRO: IQVIA	Olorofim (Pharmaceutical)	Phase IIb	Ain Shams University, Faculty of Medicine CRC (MASRI), Cairo	Inside Egypt	19/9/2022	Comply
18.	MD-004 (EZVent)	Sponsor : EZZ medical industries CRO : Dataclin	EZVent ventilator system (Medical device)	Pivotal/ Phase III	Critical Care Centre, Kasr Al Einy, Cairo University Hospital, Cairo	Inside Egypt	13/10/2022	Comply
19.	MK4482-002	Sponsor: MSD CRO: NA	Molnupiravir (Pharmaceutical)	Phase II/ III	Abbasya Fever Hospital, Cairo.	Inside Egypt	19/10/2022	Comply

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20.	M16-067	Sponsor: Abbvie CRO: NA	Risankizumab (Biological)	Phase IIb/ III	AIR force specialized hospital, Cairo	Inside Egypt	25/10/2022	Comply
21.	CLSYN.1702	Sponsor: Hamilton Health Science CRO: Clinmax	Colchicine and Spironolactone (Pharmaceutical)	Phase III/ IV	Fayoum General Hospital, Fayoum.	Inside Egypt	8/11/2022	Comply
22.	MK4482-013 MOVE-Ahead	Sponsor: MSD CRO: NA	Molnupiravir (Pharmaceutical)	Phase III	Imbaba Fever Hospital, Cairo.	Inside Egypt	16/11/2022	Comply
23.	CLSYN.1702	Sponsor: Hamilton Health Science CRO: Clinmax	Colchicine and Spironolactone (Pharmaceutical)	Phase III/ IV	Suez Canal University Hospital, Faculty of Medicine, Cardiology Department, Suez Canal.	Inside Egypt	6/12/2022	Comply
24.	CAIN457A231 0	Sponsor: Novartis CRO: MCT	Secukinumab (Biological)	Phase III	CRC (MASRI), faculty of medicine, Ain Shams university Cairo	Inside Egypt	17/1/2023	Comply
25.	SPHINX221220 20	Sponsor: Eva Pharma & Veterinary Serum & Vaccine Research Institute (VSVRI) & The Supreme Council of University Hospitals & Ministry of Higher Education	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo	Inside Egypt	1/2/2023	Comply

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		and Scientific Research						
		CRO: Dataclin						
26.	CI_Tr_1712201 9 MIRACLE- ALA	Sponsor: EVA Pharma CRO: MARC	Thiotacid (Pharmaceutical)	Phase IV	Alexandria University Hospital, Diabetes, Metabolism, and Lipidology Unit, Department of Internal Medicine, Alexandria	Inside Egypt	2/3/2023	Comply
27.	ENRICH-AF	Sponsor: Hamilton Health Science CRO: Clinmax	Edoxaban (Pharmaceutical)	Phase IV	Zagazig University Hospital, Department of Neurology, Zagazig	Inside Egypt	30/3/2023	Comply
28.	APD334-202	Sponsor: Arena Pharmaceutical (Subsidiary of Pfizer) CRO: IQVIA	Etrasimod (Pharmaceutical)	Phase II/ III	Ain Shams University, Faculty of Medicine CRC (MASRI), Cairo.	Inside Egypt	21/5/2023	Comply
29.	CLEE011A3201C	Sponsor: Novartis CRO: MCT	Ribociclib (Pharmaceutical)	Phase II	Baheya Foundation for Early Detection & Treatment of Breast Cancer, Cairo.	Inside Egypt	24/5/2023	Comply
30.	M16-066	Sponsor: Abbvie CRO: NA	Risankizumab (Biological)	Phase III	National Liver Institute, Menoufia University, Menoufia	Inside Egypt	30/5/2023	Comply
31.	CI_Tr_1712201 9	Sponsor: EVA Pharma	Thiotacid (pharmaceutical)	Phase IV	Mansoura University, Intrinsic	Inside Egypt	7/6/2023	Comply

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		CRO: MARC			Specialized Hospital, Mansoura.			
32.	COAV101B123 01	Sponsor: Novartis CRO: MCT	Zolgensma (Onasemnogene abeparvovec) (Innovative)	Phase III	Department of Neurology, Ain Shams University Specialized Hospital, Cairo	Inside Egypt	20/6/2023	Comply
33.	GBT2104-131	Sponsor: Global Blood Therapeutics /Pfizer CRO: MCT	Inclacumab (Biological)	Phase III	Clinical Research Center, Faculty of Medicine, Cairo University hospital & Abo El Rish Hospital	Inside Egypt	19/7/2023	Comply
34.	GO42784 LidERA	Sponsor: Roche CRO: MCT	Giredestrant (Pharmaceutical)	Phase III	Dar El Salam Cancer Hospital, Cairo.	Inside Egypt	30/7/2023	Comply
35.	MP-ADA1-01	Sponsor: Minapharm	Adessia (Biological)	Phase I	CRS Berlin GmbH, Germany	Outside Egypt	31/7/2023	Comply
36.	MP-ADA1-01	Sponsor: Minapharm	Adessia (Biological)	Phase I	CRS Mannheim GmbH, Germany	Outside Egypt	3/8/2023	Comply
37.	MP-ADA1-01	Sponsor: Minapharm	Bonosome (Biological)	Phase I	CRS Mannheim GmbH, Germany	Outside Egypt	4/8/2023	Comply
38.	CIPRO-001	Sponsor: Minapharm, CRO: Nagy Research	Ciprodiazole ® Tablets (Ciprofolxacin/Metr onidazole) (Innovative)	Phase III	General Syrgery department, Menoufia University Hospital, Menoufia	Inside Egypt	16/8/2023	Suspension (12/9/2022)
39.	CEGA230B240 4	Sponsor: Novartis CRO: MCT	Triclabendazole (EGATEN) (Pharmaceutical)	Phase IV	Al Mounira Children Hospital, Pediatric Hepatology Unit,	Inside Egypt	28/8/2023	Comply

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					Cairo University, Cairo.			
40.	MD-004 (EZVent)	Sponsor : EZZ medical industries CRO : Dataclin	EZVent ventilator system (Medical device)	Pivotal confirmatory phase (III)	Critical Care Unit, Kasr Al Eini Hospital, Cairo University, Cairo.	Inside Egypt	4/9/2023	Comply
41.	URSO - 003	Sponsor: Minapharm, CRO: Nagy Research	Ursoplus® capsules/ Ursofalk® capsules (Innovative)	Phase IV	Department of Endemic Diseases Medicine, Helwan University Hospital, Badr City, Cairo	Inside Egypt	14/9/2023	Comply
42.	ENRICH-AF	Sponsor: Hamilton Health Science CRO: Clinmax	Edoxaban (Pharmaceutical)	Phase IV	Fayoum General Hospital, Fayoum.	Inside Egypt	30/9/2023	Comply
43.	M16-000	Sponsor: Abbvie CRO: NA	Risankizumab (Biological)	Phase III	CRC Alexandria University Hospital, Alexandria.	Inside Egypt	2/10/2023	Comply
44.	MN39159	Sponsor: Roche CRO: IQIVIA	Ocrelizumab (Biological)	Phase III	CRC Alexandria University Hospital, Alexandria.	Inside Egypt	3/10/2023	Comply
45.	GBT440-034	Sponsor: GBT (Subsidiary of Pfizer) CRO: IQVIA	Voxelotor (Pharmaceutical)	Phase III	Zagazig University Hospital, Department of Pediatrics, Zagazig.	Inside Egypt	5/11/2023	Comply
46.	M14-430	Sponsor: Abbvie CRO: NA	Upadacitinib (ABT- 494) (Pharmaceutical)	Phase III	National Liver Institute-Menoufia University, Menoufia.	Inside Egypt	6/12/2023 7/12/2023	Comply

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47.	COAV101B123 01	Sponsor: Novartis CRO: MCT	Zolgensma (Onasemnogene abeparvovec) (Innovative)	Phase III	Department of Neurology, Ain Shams University Specialized Hospital.	Inside Egypt	13/12/2023	Comply
48.	CERE-CAP	investigator- initiated	Cerebrolysin (Biological)	Phase III	Neurology department, Ain Shams Hospital, Cairo.	Inside Egypt	26/12/2023	Termination (15/1/2024)
49.	GBT440-032	Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI	Voxelotor (Pharmaceutical)	Phase III	Al Mounira Children Hospital, Cairo University, Cairo.	Inside Egypt	28/12/2023	Comply
50.	MD-004 (EZVent)	Sponsor: EZZ medical industries CRO: Dataclin	EZVent ventilator system (Medical device)	Pivotal confirmatory phase (III)	Critical Care Unit, Kasr Al Eini Hospital, Cairo University, Cairo.	Inside Egypt	2/1/2024	Suspension (1/1/2024) Resumption (13/1/2024)
51.	CLSYN.1702	Sponsor: Hamilton Health Science CRO: Clinmax	Colchicine & Spironolactone (Pharmaceutical)	Phase III/ IV	National Heart Institute, Cairo.	Inside Egypt	7/2/2024	Comply
52.	Cl_Tr_1712201 9	Sponsor: EVA Pharma CRO: MARC	Thiotacid (pharmaceutical)	Phase IV	Beni-Suef University Hospital, Diabetes and Endocrinology Unit, Beni-Suef.	Inside Egypt	5/3/2024	Comply
53.	EMERALD-2	Sponsor: AstraZeneca CRO: IQIVIA	Durvalumab (Biological)	Phase III	Clinical Oncology dep., Faculty of medicine, Assuit university Hospital	Inside Egypt	7/3/2024	Comply

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54.	GO42784	Sponsor: Roche CRO: MCT	Giredestrant (Pharmaceutical)	Phase III	Sohag Oncology Center	Inside Egypt	4/4/2024	Compliance
55.	GBT2104-131	Sponsor: GBT/Pfizer CRO: MCT	Inclacumab (Biological)	Phase III	MASRI CRC, Ain Shams University	Inside Egypt	8/5/2024	Compliance
56.	APD334-202	Sponsor: Arena Pharmaceutical (a wholly owned subsidiary of Pfizer)	Etrasimod(Pharmace utical)	Phase III	Egyptian Liver Research Institute and Hospital	Inside Egypt	23/5/2024	Compliance
57.	GBT440-038	Sponsor: GBT (a wholly owned subsidiary of Pfizer)	Voxelotor (Pharmaceutical)	Phase III	Alexandria University, Faculty of Medicine CRC	Inside Egypt	27/6/2024	Compliance

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