



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. | SPHINX221220 20 | 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 |

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

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| 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: IQVIA | 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: IQVIA | 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 | EgyVax Vaccine (Biological) | Phase I | Al-Manial Specialized Hospital, Cairo | Inside Egypt | 10/4/2022 | Comply |

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

| | | Education and Scientific Research | | | | | | |
|-----|--------------------------|--|---|-----------|--|--------------|-----------|--------|
| | | CRO: Dataclin | | | | | | |
| 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: IQVIA | 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: IQVIA | Durvalumab (Biological) | Phase III | National hepatology and tropical medicine institute (NHTMRI), Cairo | Inside Egypt | 17/8/2022 | Comply |

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

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| 13. | SPHINX221220 20 | 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 and My lab, Cairo | Inside Egypt | 24/8/2022 25/8/2022 | Suspension Resumed |
| 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) |

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| Indicator | Blue | Pharmaceutical |
| | Orange | Medical Device |
| | Gray | Innovative |
| | Red | Herbal |

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| 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 |
| 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 | Inside Egypt | 6/12/2022 | Comply |

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| | Orange | Medical Device |
| | Gray | Innovative |
| | Red | Herbal |

| | | | | | Department, Suez Canal. | | | |
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| 24. | CAIN457A2310 | 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 and Scientific Research CRO: Dataclin | EgyVax Vaccine (Biological) | Phase I | Al-Manial Specialized Hospital, Cairo | Inside Egypt | 1/2/2023 | Comply |
| 26. | Cl_Tr_17122019 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 |

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

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| 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. | Cl_Tr_17122019 | Sponsor: EVA Pharma CRO: MARC | Thiotacid (pharmaceutical) | Phase IV | Mansoura University, Intrinsic Specialized | Inside Egypt | 7/6/2023 | Comply |

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| | Gray | Innovative |
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| | | | | | Hospital, Mansoura. | | | |
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| 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 | Phase I | CRS Mannheim GmbH, Germany | Outside Egypt | 4/8/2023 | Comply |

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

| | | | (Biological) | | | | | |
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| 38. | CIPRO-001 | Sponsor: Minapharm, CRO: Nagy Research | Ciprodiazole ® Tablets (Ciprofolxacic/Me tronidazole) (Innovative) | Phase III | General Syrgery department, Menoufia University Hospital, Menoufia | Inside Egypt | 16/8/2023 | Suspension (12/9/2022) |
| 39. | CEGA230B2404 | Sponsor: Novartis CRO: MCT | Triclabendazole (EGATEN) (Pharmaceutical) | Phase IV | Al Mounira Children Hospital, Pediatric Hepatology Unit, Cairo University, Cairo. | Inside Egypt | 28/8/2023 | Comply |
| 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 |

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| 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: IQVIA | 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 |
| 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 | Inside Egypt | 26/12/2023 | Termination (15/1/2024) |

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| | | | | | Shams Hospital, Cairo. | | | |
| 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_17122019 | 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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|-----------|--------|----------------|
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| | Orange | Medical Device |
| | Gray | Innovative |
| | Red | Herbal |