



## GCP Inspections Registry at EDA

| SN | Study Code<br>(Specified as<br>per the<br>submitted<br>protocol) | Sponsor/CRO                                                                                                                                                                                                                               | Intervention(s)<br>“Used IMPs & its<br>type (Biological,<br>Pharmaceutical,<br>Innovative, Herbal,<br>or medical device) | Study Phase<br>(I, II, III, or<br>IV) | Inspected<br>site(s)/related<br>entities                              | Country:<br>-Inside Egypt<br>-Outside<br>Egypt | Inspection<br>date | Regulatory<br>decision:<br>-Comply<br>-Suspended<br>-Terminated |
|----|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-----------------------------------------------------------------------|------------------------------------------------|--------------------|-----------------------------------------------------------------|
| 1. | CLEE011A3201C                                                    | <b>Sponsor:</b><br>Novartis<br><b>CRO:</b> MCT                                                                                                                                                                                            | Ribociclib<br><b>(Pharmaceutical)</b>                                                                                    | Phase II                              | Nasser Institute,<br>Cairo                                            | Inside Egypt                                   | 31/1/2022          | Comply                                                          |
| 2. | GBT440-032                                                       | <b>Sponsor:</b> GBT<br>(Subsidiary of<br>Pfizer)<br><b>CRO:</b> CTI                                                                                                                                                                       | Voxelotor<br><b>(Pharmaceutical)</b>                                                                                     | Phase III                             | Ain Shams<br>University, Faculty<br>of Medicine CRC<br>(MASRI), Cairo | Inside Egypt                                   | 1/2/2022           | Comply                                                          |
| 3. | SPHINX221220<br>20                                               | Sponsor: Eva<br>Pharma &<br>Veterinary Serum<br>& Vaccine<br>Research Institute<br>(VSVRI) & The<br>Supreme Council<br>of University<br>Hospitals &<br>Ministry of<br>Higher Education<br>and Scientific<br>Research<br><br>CRO: Dataclin | EgyVax Vaccine<br><b>(Biological)</b>                                                                                    | Phase I                               | Al-Manial<br>Specialized<br>Hospital,Cairo<br>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<br>CRO: PDC                                                                                                                                                                | Sputnik-Light: vector vaccine against the SARS-CoV-2 -induced coronavirus infection<br>(Biological) | Phase III     | Katameya Medical Center<br>Cairo                                       | Inside Egypt | 6/3/2022   | Comply |
| 5. | MN39159               | Sponsor: Roche<br>CRO: IQIVIA                                                                                                                                                                         | Ocrelizumab<br>(Biological)                                                                         | Phase III     | CRC (MASRI), faculty of medicine, Ain Shams university hospital, Cairo | Inside Egypt | 22/3/2022  | Comply |
| 6. | APD334-202            | <b>Sponsor:</b> Arena Pharmaceuticals (Subsidiary of Pfizer)<br><b>CRO:</b> IQVIA                                                                                                                     | Etrasimod<br>(Pharmaceutical)                                                                       | Phase II/ III | Theodor Bilharz Research Institute, Cairo                              | Inside Egypt | 23/3/ 2022 | Comply |
| 7. | SPHINX221220 20       | Sponsor: Eva Pharma & Veterinary Serum & Vaccine Research Institute (VSVRI) & The Supreme Council of University Hospitals & Ministry of Higher Education and Scientific Research<br><br>CRO: Dataclin | EgyVax Vaccine<br>(Biological)                                                                      | Phase I       | Al-Manial Specialized Hospital, Cairo                                  | Inside Egypt | 10/4/2022  | Comply |

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

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

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

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|-----|-------------------------------|----------------------------------------------------------------------------------|--------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------|--------------|-----------|--------|
|     |                               | and Scientific Research                                                          |                                |               |                                                                                                                        |              |           |        |
|     |                               | CRO: Dataclin                                                                    |                                |               |                                                                                                                        |              |           |        |
| 26. | Cl_Tr_17122019<br>MIRACLE-ALA | <b>Sponsor:</b> EVA Pharma<br><b>CRO:</b> MARC                                   | Thiotacid<br>(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                     | <b>Sponsor:</b> Hamilton Health Science<br><b>CRO:</b> Clinmax                   | Edoxaban<br>(Pharmaceutical)   | Phase IV      | Zagazig University Hospital, Department of Neurology, Zagazig                                                          | Inside Egypt | 30/3/2023 | Comply |
| 28. | APD334-202                    | <b>Sponsor:</b> Arena Pharmaceutical (Subsidiary of Pfizer)<br><b>CRO:</b> IQVIA | Etrasimod<br>(Pharmaceutical)  | Phase II/ III | Ain Shams University, Faculty of Medicine CRC (MASRI), Cairo.                                                          | Inside Egypt | 21/5/2023 | Comply |
| 29. | CLEE011A3201C                 | <b>Sponsor:</b> Novartis<br><b>CRO:</b> MCT                                      | Ribociclib<br>(Pharmaceutical) | Phase II      | Baheya Foundation for Early Detection & Treatment of Breast Cancer, Cairo.                                             | Inside Egypt | 24/5/2023 | Comply |
| 30. | M16-066                       | Sponsor: Abbvie<br>CRO: NA                                                       | Risankizumab<br>(Biological)   | Phase III     | National Liver Institute, Menoufia University, Menoufia                                                                | Inside Egypt | 30/5/2023 | Comply |
| 31. | Cl_Tr_17122019                | <b>Sponsor:</b> EVA Pharma                                                       | Thiotacid<br>(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<br>CRO: MCT                           | Zolgensma<br>(Onasemnogene abeparvovec)<br><b>(Innovative)</b>                  | 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<br>CRO: MCT  | Inclacumab<br><b>(Biological)</b>                                               | Phase III | Clinical Research Center, Faculty of Medicine, Cairo University hospital & Abo El Rish Hospital | Inside Egypt  | 19/7/2023 | Comply                 |
| 34. | GO42784 LidERA | <b>Sponsor:</b> Roche<br><b>CRO:</b> MCT                | Giredestrant<br><b>(Pharmaceutical)</b>                                         | Phase III | Dar El Salam Cancer Hospital, Cairo.                                                            | Inside Egypt  | 30/7/2023 | Comply                 |
| 35. | MP-ADA1-01     | Sponsor: Minapharm                                      | Adessia<br><b>(Biological)</b>                                                  | Phase I   | CRS Berlin GmbH, Germany                                                                        | Outside Egypt | 31/7/2023 | Comply                 |
| 36. | MP-ADA1-01     | Sponsor: Minapharm                                      | Adessia<br><b>(Biological)</b>                                                  | Phase I   | CRS Mannheim GmbH, Germany                                                                      | Outside Egypt | 3/8/2023  | Comply                 |
| 37. | MP-ADA1-01     | Sponsor: Minapharm                                      | Bonosome<br><b>(Biological)</b>                                                 | Phase I   | CRS Mannheim GmbH, Germany                                                                      | Outside Egypt | 4/8/2023  | Comply                 |
| 38. | CIPRO-001      | <b>Sponsor:</b> Minapharm,<br><b>CRO:</b> Nagy Research | Ciprodiazole ® Tablets<br>(Ciprofolxacin/Metr onidazole)<br><b>(Innovative)</b> | Phase III | General Syrgery department, Menoufia University Hospital, Menoufia                              | Inside Egypt  | 16/8/2023 | Suspension (12/9/2022) |
| 39. | CEGA230B240 4  | <b>Sponsor:</b> Novartis<br><b>CRO:</b> MCT             | Triclabendazole (EGATEN)<br><b>(Pharmaceutical)</b>                             | Phase IV  | Al Mounira Children Hospital, Pediatric Hepatology Unit,                                        | Inside Egypt  | 28/8/2023 | Comply                 |

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

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

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

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