

### Clinical Trials Registry at EDA

| S<br>N | Submission<br>date | Study<br>Code<br>(Specified<br>as per the<br>submitted<br>protocol) | Sponsor/<br>CRO   | Study title  | Study type:<br>-Interventional<br>-Observational | Study<br>Phase<br>(I, II,<br>III, or<br>IV) | Sites/activation<br>date<br>“At which the<br>clinical trials<br>will be<br>conducted in<br>Egypt”   | Status/date:<br>-Approved<br>- Recruiting<br>-Recruitment<br>completion<br>-Completed<br>-Withdrawn<br>-Suspended<br>-Terminated | Conditions /<br>Therapeutic<br>area  | Interventions<br>“Used IMPs &<br>its type<br>(Biological,<br>Pharmaceutical<br>, Innovative,<br>Herbal, or<br>medical device) |
|--------|--------------------|---|-------------------|--|--|---|---|--|--|---|
| 1-     | 27\12\2018         | M15-991   | Sponsor<br>Abbvie | A multi-center,<br>randomized,<br>double-blind,<br>placebo-controlled<br>induction study to<br>assess the efficacy<br>and safety of<br>Risankizumab in<br>subjects with<br>moderately to<br>severely active<br>Crohn’s disease<br>who failed prior<br>biologic treatment | Interventional                                   | III   | 1-CRC, faculty<br>of medicine,<br>Alexandria<br>university<br>2-CRC, faculty<br>of medicine,<br>Alexandria<br>university<br>3-Faculty of<br>medicine, Cairo<br>university<br>4- MASRI-<br>CRC, Ain<br>Shams<br>University | Approved<br>26/3/2019<br><br>Completed<br>3/11/2021  | moderately to<br>severely<br>active<br>Crohn’s<br>disease who<br>failed prior<br>biologic<br>treatment | (Biological)<br><br>Risankizumab  |

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

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|    |            |         |                   |  |                |     | 5-National<br>hepatology and<br>tropical<br>medicine<br>institute<br>6-Faculty of<br>medicine,<br>Zagazig<br>university |  |                    |                                  |
| 2- | 27\12\2018 | M16-000 | Sponsor<br>Abbvie | A Multicenter,<br>Randomized,<br>Double-Blind,<br>Placebo-<br>Controlled 52-<br>Week<br>Maintenance and<br>an Open-Label<br>Extension Study of<br>the Efficacy and<br>Safety of<br>Risankizumab in<br>Subjects with<br>Crohn's Disease<br>who respond to<br>induction<br>treatment in M16-<br>006 or M15-991 ; | Interventional | III | Two sites at<br>Faculty of<br>Medicine,<br>CRC,<br>Alexandria<br>University   | Approved<br>26/3/2019<br>Recruitment<br>completion | Crohn's<br>disease | (Biological)<br><br>Risankizumab |

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|    |           |         |                   | or completed<br>M15-989   |                |     |  |  |                                  |                                  |
| 3- | 28\2\2019 | M16-066 | Sponsor<br>Abbvie | A Multicenter,<br>Randomized,<br>Double-Blind,<br>Placebo-<br>Controlled 52-<br>Week<br>Maintenance and<br>an Open-Label<br>Extension Study of<br>the Efficacy and<br>Safety of<br>Risankizumab in<br>Subjects with<br>Ulcerative Colitis | Interventional | III | 1-Faculty of<br>medicine,<br>CRC,<br>Alexandria<br>University<br>2-CRC,<br>Alexandria<br>University<br>3-Air Force<br>Specialized<br>Hospital<br>Research<br>4- National<br>Liver Institute,<br>Menoufia<br>University | Approved<br>10/6/2019<br><br>Recruitment<br>completion | Ulcerative<br>Colitis            | (Biological)<br><br>Risankizumab |
| 4- | 28\2\2019 | M16-067 | Sponsor<br>Abbvie | Multicenter<br>randomized<br>double-blind<br>placebo-controlled<br>induction study to<br>evaluate the<br>efficacy and safety<br>of Risankizumab   | Interventional | III | 1- CRC, faculty<br>of medicine,<br>Alexandria<br>University<br>2-National<br>Liver Institute,<br>Menoufia<br>University  | Approved<br>10/6/2019<br><br>Completed:<br>30/11/2023  | Active<br>ulcerative<br>colitis. | (Biological)<br><br>Risankizumab |

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|    |          |        |                   | in subjects with moderately to severely active ulcerative colitis.  |                |     | 3-Air Force Specialized Hospital<br>4-Faculty of Medicine, CRC, Alexandria University       |                        |                               |                                 |
| 5- | 7/5/2019 | 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 | Interventional | III | 1-Faculty of medicine, Alexandria university<br>2-Faculty of medicine, Ain Shams University | Withdrawn<br>31/8/2020 | Chronic spontaneous Urticaria | (Biological)<br><br>Ligelizumab |

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| 6- | 18/9/2019  | ARTEMI<br>S-DM<br>“LPS1539<br>6” | SANOVI       | A multicenter,<br>multinational,<br>prospective,<br>interventional,<br>single-arm, Phase<br>IV study<br>evaluating the<br>clinical efficacy<br>and safety of 26<br>weeks of treatment<br>with insulin<br>glargine 300 U/mL<br>(Gla-300) in<br>patients with Type<br>2 diabetes mellitus<br>uncontrolled on<br>basal insulin | Interventional | IV | 1-Faculty of<br>medicine,<br>Alexandria<br>university<br>2-CRC,<br>Alexandria<br>university<br>3-GOTHI<br>4-Faculty of<br>medicine,<br>Menoufia<br>university<br>5-Faculty of<br>medicine, Ain<br>Shams<br>university | Approved<br>9/2/2020<br><br>Withdrawn             | Type 2<br>diabetes<br>mellitus | (Biological)<br><br>Insulin glargine<br>“Toujeo” |
| 7- | 18/11/2019 | STAND                            | NOVART<br>IS | A phase II,<br>multicenter,<br>randomized,<br>open label,<br>two arm<br>study<br>comparing<br>the effect of<br>crizanlizuma   | Interventional | II | 1-Abu El Resh<br>Children<br>Hospital   | Approved<br>5/5/2020<br><br>Withdrawn<br>3/8/2021 | Sickle cell<br>anemia          | (Biological)<br><br>Crizanlizumab                |

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|    |           |               |                      | b+ SOC alone<br>on renal<br>function in<br>sickle cell<br>disease<br>patients ≥16<br>years with<br>chronic<br>kidney<br>disease due<br>to sickle cell<br>nephropathy   |                |     |   |  |                       |                                   |
| 8- | 24/3/2020 | STEAD<br>FAST | Sponsor:<br>Novartis | A Phase III,<br>multicenter,<br>double-blind study<br>to assess efficacy<br>and safety of two<br>doses of<br>crizanlizumab vs<br>placebo with or<br>without<br>hydroxyurea /<br>hydroxycarbamide<br>therapy, in<br>adolescent and<br>adult sickle cell | Interventional | III | 1-Faculty of<br>medicine,<br>Alexandria<br>university<br>2-Faculty of<br>medicine, Ain<br>Shams<br>university | Approved<br>20/2/2020<br><br>Withdrawn<br>3/8/2021 | Sickle cell<br>anemia | (Biological)<br><br>Crizanlizumab |

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|     |           |           |                      | disease patients with vaso-occlusive crisis  |                |      |  |  |  |                                 |
| 9-  | 30/3/2020 | WA40404   | ROCHE                | A Phase III b Multicenter, Randomized, double-blind, Placebo-controlled study to evaluate the efficacy and safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis | Interventional | IIIb | 1-Sayed Galal Hospital<br>2-Faculty of medicine, Alexandria university<br>3-CRC, MASRI, Ain Shams University | Approved 23/8/2020<br><br>Withdrawn 25/8/2021  | Primary progressive multiple sclerosis | (Biological)<br><br>Ocrelizumab |
| 10- | 14/9/2020 | 1368-0025 | Boehringer Ingelheim | Open label long term extension study to assess the safety and efficacy of BI655130 treatment in patients with generalized pustular psoriasis   | Interventional | IIb  | 1-Dermatology department, faculty of medicine, Alexandria university hospital                                | Approved 18/5/2021<br><br>Withdrawn 31/10/2021 | Generalized pustular psoriasis         | (Biological)<br><br>Spesolimab  |

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| 11- | 21/9/2020 | 05-Gam-COVID-Vac-2020 | Sponsor:<br>Russian<br>Direct<br>Investmen<br>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 prophylactic treatment for SARS-COV-2 infection in Egypt | Interventional | III | 1-National liver institute, Menoufia university<br>2-CRC, faculty of medicine, Alexandria university<br>3- CRC, MASRI, Ain Shams University | Withdrawn<br>12/6/2022                              | COVID-19 prophylaxis | (Biological)<br><br>Russian Gam-COVID-Vac Combine vector vaccine |
| 12- | 22/9/2020 | CNBG20 20003SQ        | China<br>National<br>Biotec<br>Group<br>company<br>limited<br><br>Wuhan<br>institute<br>of<br>biological | 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                 | Interventional | III | 1-Vacsera Health care facility<br>2-Ktameya medical center  | Approved<br>28/3/2022<br><br>Completed<br>31/7/2022 | COVID-19 Prophylaxis | (Biological)<br><br>Inactivated SARS-COV-1 Vaccine               |

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|     |           |                                    | products<br>Co. Ltd<br>Beijin<br>institute<br>of<br>biological<br>products<br>Co.Ltd | in healthy<br>population aged 18<br>years old and<br>above   |                |     |   |   |  |  |
| 13- | 13/4/2021 | D910DC0<br>0001<br>(Emerald-<br>2) | Sponsor:<br>AstraZene<br>ca<br><br>CRO:<br>IQVIA                                     | A phase 3<br>randomized<br>double blind<br>placebo controlled<br>multicentre study<br>of durvalumab<br>monotherapy or in<br>combination with<br>bevacizumab as<br>adjuvant therapy<br>in patients with<br>hepatocellular<br>carcinoma who are<br>at high risk of<br>recurrence after<br>curative hepatic | Interventional | III | 1-CRC, Faculty<br>of medicine,<br>Alexandria<br>University<br>hospital<br>2-National<br>Liver Institute-<br>Menoufia<br>University<br>3-National<br>Hepatology &<br>Tropical<br>Medicine<br>Research<br>Institute | Approved<br>12/12/2021<br><br>Recruitment<br>completion | Hepatocellula<br>r carcinoma<br>patients at<br>high risk of<br>recurrence<br>after curative<br>hepatic<br>resection or<br>ablation | (Biological)<br><br>Durvalumab\<br>Bevacizumab |

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|     |           |                       |   | resection or ablation   |                |     | 4-Air Force specialized Hospital<br>5-Faculty of medicine, Assuit University     |   |                      |  |
| 14- | 19/5/2021 | 01-Sputnik-Light-2021 | Sponsor: Human vaccine LLC (Global), Russian ministry of healthcare – Gamalya (Local)<br><br>CRO: PDC | A phase III, randomized, double-blind, placebo-controlled international multi-site clinical trial in parallel assignment to evaluate efficacy, immunogenicity and safety of the Sputnik Light vector vaccine in adults in the SARS-Cov-2 infection prophylactic treatment | Interventional | III | 1- National hepatology and tropical medicine center<br>2-Katemeya medical center | Approved 24/8/2021<br><br>Completion of study visit 31/8/2022 | COVID-19 Prophylaxis | (Biological)<br><br>Sputnik Light vector vaccine |
| 15- | 25/5/2021 | KATE-3                | Sponsor: ROCHE  | A randomized, multi-center,   | Interventional | III | 1-Faculty of medicine, Kasr  | Approved 5/12/2021  | HER2-positive and    | (Biological)                                     |

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|     |           |                   |                      | double blind,<br>placebo-controlled<br>phase III study of<br>the efficacy and<br>safety of<br>Trastuzumab<br>Emtansine in<br>combination with<br>Atezolizumab or<br>placebo in Pts with<br>HER2-positive<br>and PD-L1-<br>positive locally<br>advanced or<br>metastatic breast<br>cancer who have<br>received prior<br>Trastuzumab +<br>Atezolizumab and<br>Taxane- based<br>therapy |                |     | Al-Ainy<br>hospital<br>2-Shefaa Al-<br>Orman hospital<br>3-Baheya<br>Hospital | Withdrawn<br>19/12/2022 | PD-L1-<br>positive<br>locally<br>advanced or<br>metastatic<br>breast cancer | Trastuzumab<br>Emtansine/<br>Atezolizumab |
| 16- | 27/5/2021 | CAIN457<br>P12301 | Sponsor:<br>Novartis | A randomized,<br>double blind,<br>placebo-<br>controlled, parallel<br>group, phase III<br>multi-center study   | Interventional | III | 1-CRC, Faculty<br>of medicine,<br>Alexandrian<br>university                   | Withdrawn<br>3/11/2021  | Active<br>ankylosing<br>spondylitis   | (Biological)<br>Secukinumab               |

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|     |          |           |                               | 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 |                |     |   |                     |                      |  |
| 17- | 5/8/2021 | TG2101V01 | Sponsor: Livzon mabpharm Inc. | A Global, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Recombinant SARS-CoV-2 Fusion Protein                             | Interventional | III | 1-National Hepatology and Tropical Medicine Research Institute (NHTMRI) | Withdrawn 16/1/2022 | COVID-19 Prophylaxis | (Biological)<br><br>Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01) |

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|     |           |              |  | Vaccine (V-01) in Adults Aged 18 Years and Older",   |                |     |                                |   |                          |   |
| 18- | 18/8/2021 | 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 | Interventional | III | Air force specialized hospital | Approved 2/2/2022<br><br>Recruitment completion | Hepatocellular carcinoma | (Biological)<br><br>Atezolizumab/<br>Lenvatinib/<br>Sorafenib |
| 19- | 2/9/2021  | COVID_VACC_1 | Sponsor: National research center<br><br>CRO: CLINMA X | A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Inactivated SARS-CoV-2 Vaccine Against COVID-19 in Healthy Adults   | Interventional | I   | National research center       | Approved 9/11/2021<br><br>Suspended 9/12/2021   | Covid-19 Prophylaxis     | (Biological)<br><br>Inactivated SARS-CoV-2 Vaccine            |

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| 20- | 17/1/2022 | SPHINX-EGYPT<br>SPHINX2<br>2122020 | Sponsor:<br>- EVA<br>PHARMA<br>- VSVRI<br>- supreme council of university hospitals<br>- Ministry of higher education and scientific research<br><br>CRO:<br>Dataclin | Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2 Infection (COVID-19)   | Interventional | I   | Al-Manial specialized university Hospital, Cairo university hospitals   | Approved 3/2/2022<br><br>Database lock 26/9/2023 | Covid-19 Prophylaxis                                    | (Biological)<br><br>EgyVax     |
| 21- | 4/11/2021 | GBT2104-131                        | Sponsor:<br>Global blood therapeutics Inc. \ Pfizer<br><br>CRO:<br>MCT  | A randomized double blinded placebo controlled multicentre study to access the safety and efficacy of Inclacumab in participants with sickle cell disease experiencing | Interventional | III | 1-Faculty of medicine, Mansoura University<br>2-Faculty of medicine, Zagazig University<br>3-MASRI-CRC, Faculty | Approved 14/6/2022<br><br>Recruitment completion | sickle cell disease patients with Vaso-occlusive crisis | (Biological)<br><br>Inclacumab |

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|     |          |                 |  | Vaso-occlusive crisis          |                |     | of medicine,<br>Ain Shams<br>University<br>hospital<br>4-CRC,<br>Alexandria<br>University<br>5- Pediatric<br>hematology<br>department,<br>Alexandria<br>University<br>6. CRC, faculty<br>of medicine,<br>Cairo<br>University,<br>Abo El-Resh<br>Hospital<br>7- CRC, Cairo<br>University<br>8- Hematology<br>department,<br>Cairo<br>University<br>hospital |                       |                        |              |
| 22- | 4/1/2022 | GBT2104<br>-132 |  | A Randomized,<br>Double-blind, | Interventional | III | 1. Faculty of<br>medicine,   | Approved<br>14/6/2022 | Sickle cell<br>disease | (Biological) |

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|  |  |  | Global<br>blood<br>therapeuti<br>cs Inc.\<br>Pfizer<br><br>CRO:<br>MCT | Placebo-<br>controlled,<br>Multicenter Study<br>of a Single Dose<br>of Inclacumab to<br>Reduce Re-<br>admission in<br>Participants with<br>Sickle Cell<br>Disease and<br>Recurrent Vaso-<br>occlusive Crises<br>(GBT-132) |  |  | Mansoura<br>University<br>2. Faculty of<br>medicine,<br>Zagazig<br>University<br>3. MASRI,<br>CRC, Ain<br>Shams<br>University<br>4. Hematology<br>unit, Internal<br>medical<br>department,<br>CRC, faculty of<br>medicine<br>Alexandria<br>University<br>hospital<br>5- Hematology<br>department,<br>Alexandria<br>University<br>hospital<br>6. Cairo<br>University, | Withdrawn<br>29/6/2023 | patients with<br>Vaso-<br>occlusive<br>crisis | Inclacumab |
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|           | Orange | Medical Device |
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|     |            |             |  |  |                |     | Abo El-Resh Hospital<br>7- CRC, Cairo University<br>8- Cairo University, Hematology department.  |  |                     |  |
| 23- | 28/11/2021 | GBT2104-133 | Global blood therapeutics Inc.\ Pfizer<br><br>CRO: MCT | An Open-label Extension Study to Evaluate the Long-term Safety of Inclacumab Administered to Participants with Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial | Interventional | III | 1. Faculty of medicine, Mansoura University<br>2. Faculty of medicine, Zagazig University<br>3. MASRI, CRC, Ain Shams University<br>4. Hematology unit, Internal medical department, CRC, faculty of medicine Alexandria | Approved 14/6/2022<br><br>Withdrawn 17/12/2023 | sickle cell disease | (Biological)<br><br>Inclacumab/<br>Placebo |

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|     |          |                        |  |  |                |     | University hospital<br>5- Hematology department,<br>Alexandria University hospital<br>6. Cairo University,<br>Abo El-Resh Hospital<br>7- CRC, Cairo University<br>8- Cairo University,<br>Hematology department. |  |                                |                                 |
| 24- | 8\6\2022 | Consonance-<br>MN39159 | Sponsor:<br>F.HOFFMANN-LA ROCHE LTD<br><br>CRO:<br>Roche Egypt LLC & | An open-label, single-arm 4-year study to evaluate effectiveness and safety of ocrelizumab treatment in patients with progressive multiple sclerosis | Interventional | III | 1-CRC, Faculty of Medicine, Alexandria university, CRC<br>2-MASRI-CRC,faculty of medicine, Ain Shams   | Approved 20/9/2022<br><br>Recruitment completion | Progressive multiple sclerosis | (Biological)<br><br>Ocrelizumab |

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|     |           |                                 | IQVIA<br>(for<br>monitorin<br>g activities<br>only)   |  |                |         | university<br>hospital   |                        |   |  |
| 25- | 9\2\2022  | 20200404<br>(IMBCA<br>M         | Sponsor:<br>Institute<br>of<br>Medical<br>Biology<br>Chinese<br>Academy<br>of<br>Medical<br>Sciences<br><br>CRO:<br>PDC | A randomized<br>double-blinded<br>placebo-controlled<br>Phase III clinical<br>trial of SARS-<br>COV-2 vaccine<br>inactivated<br>(Vero cell) in<br>adult aged 18<br>years and above | Interventional | III     | 1-Katameya<br>Medical Center<br>2- National<br>Hepatology and<br>tropical<br>medicine<br>institute           | Withdrawn<br>24/2/2022 | Covid-19<br>Prophylaxis   | (Biological)<br><br>Inactivated<br>SARS-COV-2<br>vaccine |
| 26- | 10/5/2022 | TRISTAR<br>DS-<br>0135-<br>0347 | Sponsor:<br>Boehringer<br>Ingelheim<br><br>CRO:<br>MCT  | The TRISTARDS<br>trial -Thrombolysis<br>Therapy for<br>ARDS A Phase<br>IIb/III<br>operationally<br>seamless, open-<br>label, randomized,<br>sequential,                            | Interventional | IIb/III | 1.National<br>Hepatology and<br>Tropical<br>Medicine<br>Research<br>Institute<br>2.Abbasia<br>Fever Hospital | Withdrawn<br>20/7/2022 | Respiratory<br>distress<br>syndrome<br>(ARDS)<br>triggered by<br>COVID-19 | (Biological)<br><br>Alteplase                            |

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| Blue   | Pharmaceutical |
| Orange | Medical Device |
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|     |           |               |                                   | parallel-group adaptive study to evaluate the efficacy and safety of daily intravenous alteplase treatment given up to 5 days on top of standard of care (SOC) compared with SOC alone, in patients with acute respiratory distress syndrome (ARDS) triggered by COVID-19. |                |     | 3.Imbaba Fever Hospital  |   |   |                                 |
| 27- | 14/8/2022 | CAIN457 A2310 | Sponsor: Novartis<br><br>CRO: MCT | A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous Secukinumab compared to   | Interventional | III | 1-CRC, Faculty of Medicine, Alexandria university hospital<br>2-Dermatology department, faculty of Medicine, Ain Shams | Approved 4/12/2022<br><br>Early terminated by sponsor 31/3/2023 | Treatments of severe chronic plaque psoriasis | (Biological)<br><br>Secukinumab |

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|     |           |                |                                   | placebo and etanercept (in a single blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis |                |     | University hospital  |                        |                      |   |
| 28- | 8/11/2022 | SCTV01E-MRCT-1 | Sponsor: Sinocelltech<br>CRO: PDC | A randomized double blind positive controlled phase III clinical trial to evaluate the efficacy and safety of SCTV01E (a covid-19alpha/beta/delta/omicron variants s-trimmer vaccine) in population                                   | Interventional | III | 1-Katemya Medical Center<br>2-Egyptian Liver research institute and hospital | Withdrawn<br>14/1/2023 | COVID-19 prophylaxis | (Biological)<br><br>SCTV 01E (a covid-19 alpha/beta/delta/omicron variants s-trimmer vaccine)<br>(Biological) |

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|     |          |                           |  | previously<br>unvaccinated with<br>COVID-19<br>vaccine and aged<br>≥18   |                |     |   |   |   |                                |
| 29- | 6/6/2023 | FUZION<br>CNT019<br>59CRD | Sponsor:<br>Janssen<br><br>CRO:<br>MCT | A Phase 3,<br>Randomized,<br>Placebo-<br>controlled,<br>Parallel-group,<br>Multicenter Study<br>to Evaluate the<br>Efficacy and<br>Safety of<br>Guselkumab in<br>Participants with<br>Fistulizing,<br>Perianal Crohn's<br>Disease "FUZION<br>CD" | Interventional | III | 1.National<br>Hepatology<br>Tropical<br>Medicine<br>Research<br>Institute<br>2.CRC, faculty<br>of medicine<br>Alexandria<br>university<br>hospital, (two<br>sites)<br>3. Department<br>of internal<br>medicine, El<br>Kasr Al Aini,<br>Cairo<br>University<br>4. MASRI<br>CRC, faculty of<br>medicine, Ain<br>Shams | Approved<br>13/8/2023<br><br>Recruiting | Fistulizing<br>perianal<br>Crohn's<br>disease | Guselkumab<br><br>(Biological) |

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| Color<br>Indicator | Green  | Biological     |
|                    | Blue   | Pharmaceutical |
|                    | Orange | Medical Device |
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|     |                |                      |  |  |                |        | University<br>Hospital  |   |  |                             |
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| 30- | MP-<br>ADA1-01 | 14/5/2023            | Sponsor:<br>Minaphar<br>m<br>CRO:<br>CRS<br>Clinical<br>Research<br>Services<br>Berlin<br>GmbH | A Phase I,<br>randomized,<br>double-blind, 2-<br>arm, parallel group<br>trial to compare<br>pharmacokinetics<br>of Adessia with<br>EU-authorized<br>Humira in healthy<br>male and female<br>participants”                  | Interventional | I      | -CRS clinical<br>research<br>services, Berlin<br>GmbH<br>-CRS clinical<br>research<br>services,<br>Mannheim<br>GmbH   | Approved<br>10/8/2023<br><br>Completed  | Inflammatory<br>disease<br>(Biosimilar to<br>Humira) | Adessia<br><br>(Biological) |
| 31- | 4/5/2023       | MOM-<br>M281-<br>006 | Sponsor:<br>Janssen<br><br>CRO:<br>MCT   | Efficacy and<br>Safety of M281 in<br>Adults with Warm<br>Autoimmune<br>Hemolytic<br>Anemia: A<br>Multicenter,<br>Randomized,<br>Double-blind,<br>Placebo-controlled<br>Study with a<br>Long-term Open-<br>label Extension” | Interventional | II\III | -National<br>Cancer Institute,<br>Cairo university<br>-Oncology<br>center,<br>Mansoura<br>University<br>Hospital<br>-Department of<br>internal<br>medicine, Al<br>Kasr al Eini,<br>Cairo university | Approved<br>19/7/2023<br><br>Recruiting | Warm<br>Autoimmune<br>Hemolytic<br>Anemia            | M281<br><br>(Biological)    |

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|     |  |                                   |   |   |                |     | -Naser institute<br>hospital for<br>research and<br>treatment<br>-CRC, faculty of<br>medicine,<br>Alexandria<br>university<br>Hospital<br>-CRC, faculty of<br>medicine, Ain<br>shams university<br>Hospital |  |   |   |
| 32- | 9\10/2023<br><br>shift to<br>amendment<br>submission<br>26\12\2023 | EMERAL<br>D-3)<br>D910VC0<br>0001 | Sponsor:<br>AstraZene<br>ca<br>CRO:<br>IQIVIA | A Phase III,<br>Randomized,<br>Open-Label,<br>Sponsor-Blinded,<br>Multicenter Study<br>of Durvalumab in<br>Combination<br>with<br>Tremelimumab<br>± Lenvatinib Given<br>Concurrently with<br>Transarterial<br>Chemoembolization | Interventional | III | - Air Force<br>specialized<br>hospital<br>- Oncology<br>department,<br>Faculty of<br>medicine, Alex<br>University<br>- Egyptian<br>liver Hospital<br>- National<br>Hepatology<br>and Tropical<br>Medicine   | Approved<br>8/2/2024<br><br>Recruiting | Locoregional<br>Hepatocellular<br>Carcinoma | (Biological)<br><br>Durvalumab /<br>Tremelimumab/<br>Lenvatinib /TACE |

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|     |                          |          |  | (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)   |                |     | Research Institute (NHTMRI) - Shifa El orman Hospital                                 |                                 |                              |  |
| 33- | not submitted officially | CERE-CAP | investigat or-initiated                  | Efficacy of Cerebrolysin as an adjuvant therapy following mechanical thrombectomy in patients with large vessels occlusion stroke                  | Interventional | III | Neurology and psychiatry department, Ain Shams University Hospital                    | Terminated (by EDA) (15/1/2024) | occlusion stroke             | (Biological) CEREBROLY SIN solution for IM or IV injection/ concentrate for solution for I.V. infusion |
| 34- | 14/12/2023               | BCD-178  | Sponsor: JSC BIOCAD<br><br>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 | Interventional | III | -Faculty of Medicine, Aleandria UNIVERSITY<br>-Faculty of Medicine , Cairo University | Approved: 22/4/2024             | Her-2 positive breast cancer | Biological BCD-178   |

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| 35- | 8/1/2024 | SerpinPc 102         | Sponsor: Apcintex<br><br>CRO: MCT | A Global, Open-label, 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) | Interventional | Iib | Ain Shams University Medical Research Institute (MASRI) | Conditional Approved 13/6/2024<br><br>Final Approval 31/10/2024 | Hemophilia A or Moderately Severe to Severe Hemophilia B | Biological<br><br>SerpinPC 102  |
| 36- | 8/1/2024 | SerpinPC 103         | Sponsor: Apcintex<br><br>CRO: MCT | A Global, Open-label Study to Investigate the Efficacy and Safety of SerpinPC in Subjects with Hemophilia B with Inhibitors (AP-0103)   | Interventional | Iib | Ain Shams University Medical Research Institute (MASRI) | Conditional Approved 13/6/2024<br><br>Final Approval 31/10/2024 | Hemophilia B with Inhibitors                             | Biological<br><br>Serpin PC 103 |
| 37- | 8/2/2024 | D9185C00 001'TILI A' | Sponsor: AstraZenca               | A Phase III, Multicenter, Randomized,   | Interventional | III | 1-Air Force specialized Hospital                        | Approved: 4/8/2024  | Patients hospitalized                                    | Biological                      |

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| Color Indicator | Green  | Biological     |
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|     |            |                  | CRO:<br>IQVIA                       | Double-bind,<br>Parallel-group,<br>Placebo-<br>Controlled study<br>to evaluate the<br>efficacy and safety<br>of Tozoralmab<br>(MEDI3506) in<br>patients<br>hospitalized for<br>viral lung infection<br>requiring<br>supplemental<br>oxygen |                |    | 2-Ain Shams<br>University<br>Medical<br>research<br>Institute<br>(MASRI-CRC)<br>3-CRC,<br>Alexandria<br>University<br>Hospital  |   | for viral lung<br>infection | Tozoralmab  |
| 38- | 17/12/2020 | CEGA23<br>0B2404 | Sponsor:<br>Novartis<br>CRO:<br>MCT | A Phase IV<br>Multicenter Open<br>Label Study to<br>Determine the<br>Safety,<br>Tolerability and<br>Clinical Outcomes<br>Following Oral<br>Administration of<br>Egaten<br>(Triclabandazole)<br>in Patients 6 Years<br>of Age or Older      | Interventional | IV | 1-Cairo<br>University, Al<br>Mounira<br>Children<br>Hospital,<br>Pediatric<br>Hepatology<br>Unit.<br>2-Alexandria<br>University,<br>Faculty of<br>Medicine,<br>Clinical | Approved<br>12/4/2021<br><br>Recruiting | Fascioliasis                | (Pharmaceutical)<br><br>Triclabandazole<br>(Egaten) |

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|     |            |                                      |                                     | with Fascioliasis<br>(Egaten)   |                |     | Research<br>Center.   |   |                                       |   |
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| 39- | 22/12/2020 | CLEE011<br>A3201C<br>RIGHT<br>Choice | Sponsor:<br>Novartis<br>CRO:<br>MCT | A Phase II<br>Randomized Study<br>of the<br>Combination of<br>Ribociclib Plus<br>Goserelin Acetate<br>with Hormonal<br>Therapy Versus<br>Physician Choice<br>Chemotherapy in<br>Premenopausal or<br>Perimenopausal<br>Patients with<br>Hormone<br>Receptor-<br>Positive/HER2-<br>Negative<br>Inoperable Locally<br>Advanced or<br>Metastatic Breast<br>Cancer - RIGHT<br>Choice Study | Interventional | II  | 1-Ain Shams<br>University,<br>Faculty of<br>Medicine,<br>Clinical<br>Research<br>Center,<br>(MASRI –<br>CRC)<br>2-Baheya<br>Hospital<br>Research<br>Center<br>3-Cairo<br>University,<br>NEMROCK<br>4-Nasser<br>Institute Cancer<br>Center | Approved<br>14/10/2021<br><br>Completed<br>8/1/2023 | HER-2<br>Negative<br>Breast<br>Cancer | (Pharmaceutical)<br><br>Ribociclib Plus<br>Goserelin /<br>Physician<br>Choice<br>Chemotherapy |
| 40- | 24/10/2021 | M14-430                              | Sponsor:<br>Abbvie<br>CRO: NA       | A Multicenter,<br>Randomized,<br>Double-Blind,  | Interventional | III | 1-Air Force<br>Specialized<br>Hospital  | Approved<br>7/7/2022                                | Chron's<br>Disease                    | (Pharmaceutical)  |

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|     |            |                  |                              | Placebo-<br>Controlled<br>Maintenance and<br>Long-Term<br>Extension Study of<br>the Efficacy and<br>Safety of<br>Upadacitinib<br>(ABT-494) in<br>Subjects with<br>Crohn's Disease<br>Who Completed<br>the Studies M14-<br>431 or M14-433 |                |     | 2-National Liver<br>Institute<br>Menoufiya<br>University<br>3-Alexandria<br>University,<br>Faculty of<br>Medicine,<br>Clinical<br>Research Center.<br>4-Ain Shams<br>University,<br>Faculty of<br>Medicine,<br>Clinical<br>Research Center<br>(MASRI-CRC). | Recruitment<br>Completion                              |             | Upadacitinib/<br>matching<br>placebo                                  |
| 41- | 26/10/2021 | BO40336<br>ALINA | Sponsor:<br>Roche<br>CRO: NA | A Phase III, Open-<br>Label,<br>Randomized Study<br>to Evaluate the<br>Efficacy and<br>Safety of Adjuvant<br>Alectinib Versus<br>Adjuvant<br>Platinum-Based<br>Chemotherapy in   | Interventional | III | 1- Cairo<br>University, Kasr<br>Al Eini, Center<br>of Radiation<br>Oncology and<br>Nuclear<br>Medicine.  | Approved<br>16/3/2022<br><br>Recruitment<br>Completion | Lung Cancer | (Pharmaceutical)<br><br>Alectinib /<br>Platinum based<br>Chemotherapy |

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|     |            |                                       |   | Patients with Completely Resected Stage Ib (Tumors $\geq$ 4 Cm) To Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer  |                |    |   |   |  |   |
| 42- | 12/12/2021 | Cl_Tr_17<br>122019<br>MIRACL<br>E-ALA | Sponsor:<br>EVA<br>Pharma<br>CRO:<br>MARC | A Multicenter, Interventional, Two-Arm, Parallel-Group, Randomized, Double-Blinded, Placebo-Controlled, Phase IV Trial to Evaluate the Efficacy of Alpha-Lipoic Acid in the Treatment of Patients with Symptomatic Diabetic | Interventional | IV | 1- Alexandria University Hospital, Diabetes, Metabolism, and Lipidology Unit, Department of Internal Medicine.<br>2- Ain Shams University Hospital<br>3- Menoufiya University Hospital<br>4- Mansoura University, | Approved<br>12/10/2022<br><br>Completed<br>11/12/2024 | Treatment of Symptomatic Diabetic Polyneuropathy | (Pharmaceutical)<br><br>Alpha-Lipoic Acid (Thiotacid)/ matching placebo |

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|     |            |                          |                         | Polyneuropathy in Egypt  |                |     | Intrinsic Specialized Hospital.<br>5- Beni-Suef University Hospital,<br>Diabetes and Endocrinology Unit.   |  |                         |   |
| 43- | 12/12/2021 | MK4482-013<br>MOVE-Ahead | Sponsor: MSD<br>CRO: NA | A Phase 3 Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of MK-4482 for the Prevention of COVID-19 (Laboratory Confirmed SARS-COV 2 Infection with Symptoms) in Adults. | Interventional | III | 1-Ain Shams University Clinical Research Center (MASRI-CRC).<br>2-Air Force Specialized Hospital.<br>3-National Hepatology and Tropical Medicine Research Institute.<br>4-Imbaba Fever Hospital. | Approved 18/1/2022<br><br>Completed 16/11/2022 | Prophylaxis of COVID-19 | (Pharmaceutical)<br><br>Molnupiravir/<br>matching placebo |

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|     |           |            |  |  |                |     | 5-National Center for Allergies and Chest Imbaba  |  |                     |  |
| 44- | 30/3/2022 | GBT440-032 | Sponsor: GBT (Subsidiary of Pfizer) CRO: CTI | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Voxelotor (GBT440) in Pediatric Participants with Sickle Cell Disease (HOPE Kids 2) | Interventional | III | 1-Ain Shams University Clinical Research Center (MASRI-CRC).<br>2-Alexandria University Clinical Research Center.<br>3- Al Mounira Children Hospital, Cairo University,<br>4-Zagazig University Hospital, Department of Pediatrics. | Approved 31/7/2022<br><br>IMP Dosing Pause 02/05/2024<br>Early Termination by the sponsor 29/09/2024 | Sickle Cell Disease | (Pharmaceutical)<br><br>Voxelotor/<br>matching placebo |
| 45- | 18/4/2022 | GBT440-034 | Sponsor: GBT                                 | An Open Label Extension Study of   | Interventional | III | 1-Cairo University,   | Approved   | Sickle Cell Disease | (Pharmaceutical)                                       |

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|     |           |              | (Subsidiary of Pfizer)<br>CRO: IQVIA | GBT440 Administered Orally to Patients with Sick Cell Disease who Have Participated in GBT440 Clinical Trials                             |                |     | Abu El Rich Hospital.<br>2-Ain Shams University Clinical Research Center (MASRI-CRC)<br>3-Alexandria University Clinical Research Center<br>4-Zagazig University Hospital, Department of Pediatrics. | 2/8/2022<br><br>Early Termination by the sponsor<br><br>30/09/2024 |                           | Voxelotor                        |
| 46- | 17/5/2022 | F901318/0032 | Sponsor: F2G<br>CRO: IQVIA           | Open Label Single Arm Phase IIb Study of F901318 as Treatment of Invasive Fungal Infections Due to Lomentospora Prolificans, Seedosporium | Interventional | IIb | 1-Mansoura University Oncology center<br>2-Alexandria University, Clinical Research Center   | Terminated (By Sponsor)<br>24/7/2022                               | Invasive Fungal Infection | (Pharmaceutical)<br><br>Olorofim |

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|     |           |                                 |  | Spp., Aspengillus<br>Spp., & other<br>Resistant Fungi in<br>Patients Lacking<br>Suitable<br>Alternative   |                |        | 3-Nasser<br>Institute<br>4-Ain Shams<br>University<br>Clinical<br>Research<br>Center,<br>(MASRI –<br>CRC)<br>5-Air Force<br>specialized<br>Hospital<br>6-National<br>Cancer Institute<br>7-Cairo<br>University Kasr<br>Al-Eini,<br>Hospital |  |   |   |
| 47- | 12/6/2022 | CLSYN.1<br>702<br>(OASIS-<br>9) | Sponsor:<br>Hamilton<br>Health<br>Science<br>CRO:<br>Clinmax | A 2x2 Factorial<br>Randomized<br>Controlled Trial of<br>CoLchicine and<br>spironolactonE in<br>Patients With<br>myocARDial<br>infarction/SYNER<br>GY Stent Registry | Interventional | III/IV | 1-Mansoura<br>University<br>Hospital<br>2-Suez Canal<br>University<br>Hospital<br>3-Fayoum<br>General<br>Hospital   | Approved<br>24/7/2022<br><br>Completed<br>01/08/2024 | STEMI/Non-<br>STEMI<br>Myocardial<br>Infarction | (Pharmaceutical)<br><br>Colchicine,<br>Spironolactone/<br>matching<br>placebo |

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|     |           |             |   | – Organization to Assess Strategies for Ischemic Syndromes 9  |                |        | 4-Tamia Central Hospital<br>5-El Kharga Specialized Hospital<br>6-National Heart Institute |   |   |  |
| 48- | 15/6/2022 | 20140106    | Sponsor: Onyx Pharmaceuticals (Subsidiary of Amgen)<br>CRO: IQVIA | Phase 1b/2 Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia | Interventional | Ib/II  | 1-Children's Cancer Hospital 57357   | Approved 23/8/2022<br><br>Withdrawn 19/6/2023 | Relapsed or Refractory Acute Lymphoblastic Leukemia | (Pharmaceutical)<br><br>Carfilzomib                  |
| 49- | 18/7/2022 | AG348-C-020 | Sponsor: Agios<br>CRO: MCT  | A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of                             | Interventional | II/III | 1-Alexandria University Clinical Research Center<br>2-Zagazig University Hospital          | Approved 27/9/2022<br><br>Withdrawn 21/8/2023 | Sickle Cell Disease                                 | (Pharmaceutical)<br><br>Mitapivat / matching placebo |

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

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|     |           |              |                            | Mitapivat in Subjects with Sickle Cell Disease   |                |     | 3-Cairo University Hospital<br>4-Mansoura University Hospital<br>5-Ain Shams University Clinical Research Center (MASRI-CRC)                                      |                     |   |   |
| 50- | 26/7/2022 | F901318/0041 | Sponsor: F2G<br>CRO: IQVIA | A Phase III, Adjudicator-Blinded, Randomised Study to Evaluate the Efficacy and Safety of Treatment with Olorofim Versus Treatment with Ambisome® Followed by Standard of Care (SOC) in Patients with Invasive | Interventional | III | 1-Mansoura University Oncology Center<br>2-Alexandria University Clinical Research Center<br>3-Air Force specialized Hospital<br>4-Ain Shams University, Clinical | Approved 11/10/2022 | Invasive Fungal Disease caused by Aspergillus species | (Pharmaceutical)<br><br>Olorofim / Ambisome |

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

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|     |           |            |   | Fungal Disease (IFD) Caused by Aspergillus Species  |                |     | Research Center (MASRI-CRC) 5-Zagazig University Hospital 6-National Cancer Institute 7-Cairo University Kasr Al Eini Hospital 8-Nasser Institute for Research and Treatment |  |   |  |
| 51- | 27/7/2022 | APD334-202 | Sponsor: Arena Pharmaceuticals (Subsidiary of Pfizer) | A Multicenter Randomized Double Blinded Parallel Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for | Interventional | III | 1-Alexandria University Clinical Research Center 2-Air Force Specialized Hospital 3-National Liver Institute   | Approved 23/8/2022<br><br>Recruitment Completion | Moderately to Severe Active Crohn's Disease | (Pharmaceutical)<br><br>Etrasimod / matching placebo |

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| Orange | Medical Device |
| Gray   | Innovative     |
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|     |          |                             |                               | Moderately to Severe Active Crohn's Disease (Etrasimod)       |                |     | 4-National Hepatology and Tropical Medicine Research Institute (NHTMRI)<br>4-Cairo University Kasr Al-Eini Hospital<br>5-Egyptian Liver Research Institute and Hospital<br>6-Ain Shams University Hospital<br>7-Theodor Bilharz Research Institute |                        |                              |   |
| 52- | 7/8/2022 | EFC1721<br>5<br>LEAP-2-MONO | Sponsor:<br>Sanofi<br>CRO: NA | A Phase 3, Multicenter, Multinational Randomized Double-Blind | Interventional | III | 1-Alexandria University Hospital Clinical  | Approved<br>24/10/2022 | Gaucher Disease Type 3 (GD3) | (Pharmaceutical)<br><br>Venglustat/<br>Cerezyme |

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

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|     |           |             |                            | Double-Dummy, Active Comparator Study to Evaluate the Efficacy and Safety of Venglustat in Adult and Pediatric Patients with Gaucher Disease Type 3 (GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy |                |     | Research Center   |   |   |  |
| 53- | 15/8/2022 | AG348-C-017 | Sponsor: Agios<br>CRO: MCT | A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in  | Interventional | III | 1-Cairo University Hospital<br><br>2-Ain Shams University Clinical Research Center<br>MASRI-CRC | Approved 2/11/2022<br><br>Withdrawn 26/6/2023 | Non-Transfusion-Dependent Alpha or Beta Thalassemia | (Pharmaceutical)<br><br>Mitapivat / matching placebo |

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

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|     |           |              |                             | Subjects with Non-Transfusion-Dependent Alpha- or Beta- Thalassemia (ENERGIZE)   |                |     |  |   |   |   |
| 54- | 15/8/2022 | AG348-C-018  | Sponsor: Agios<br>CRO: MCT  | A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Transfusion-Dependent Alpha- or Beta- Thalassemia (ENERGIZE-T) | Interventional | III | 1-Cairo University Hospital<br><br>2-Ain Shams University Clinical Research Center MASRI-CRC | Approved 2/11/2022<br><br>Withdrawn 26/6/2023 | Transfusion-Dependent Alpha or Beta Thalassemia | (Pharmaceutical)<br><br>Mitapivat / matching placebo  |
| 55- | 29/8/2022 | 4202-HEM-301 | Sponsor: Forma Therapeutics | An Adaptive, Randomized, Placebo-Controlled, Double-blind,   | Interventional | III | 1- Alexandria University Clinical Research Center  | Approved 11/12/2022<br><br>Recruiting         | Sickle Cell Disease                             | (Pharmaceutical)<br><br>Etavopivat / matching placebo |

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|                 | Blue   | Pharmaceutical |
|                 | Orange | Medical Device |
|                 | Gray   | Innovative     |
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|     |           |                   | CRO:<br>MCT                      | Multi-center Study<br>of Oral<br>Etavopivat, a<br>Pyruvate Kinase<br>Activator in<br>Patients with<br>Sickle Cell<br>Disease  |                |     | 2-Zagazig<br>University<br>Hospital<br>3-Cairo<br>University<br>Hospital<br>4-Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>(MASRI-CRC)  |  |   |  |
| 56- | 29/9/2022 | GO42784<br>LIDERA | Sponsor:<br>Roche<br>CRO:<br>MCT | A Phase III,<br>Randomized,<br>Open-Label,<br>Multicenter Study<br>Evaluating the<br>Efficacy and<br>Safety of Adjuvant<br>Giredestrant<br>Compared with<br>Physician's Choice<br>of Adjuvant<br>Endocrine<br>Monotherapy in<br>Patients with<br>Estrogen | Interventional | III | 1-Alexandria<br>University<br>Hospital<br>2-Medical<br>Research<br>Institute,<br>Alexandria<br>University<br>3-Mansoura<br>University<br>Hospital<br>4-Cairo<br>University Kasr<br>Al- Ainy<br>Hospital | Approved<br>4/12/2022<br><br>Recruitment<br>Completion | <b>Estrogen<br/>Receptor<br/>-Positive<br/>, Her2-<br/>Negative<br/>Early<br/>Breast<br/>Cancer</b> | (Pharmaceutical)<br><br>Giredestrant /<br>Physician<br>Choice of<br>Adjuvant<br>Endocrine<br>Monotherapy |

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| Color     | Green  | Biological     |
| Indicator | Blue   | Pharmaceutical |
|           | Orange | Medical Device |
|           | Gray   | Innovative     |
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|     |            |                          |                                       | Receptor-Positive,<br>Her2-Negative<br>Early Breast<br>Cancer   |                |     | 5-Ain Shams<br>University<br>Demerdash<br>Hospital<br>6- Dar El<br>Salam Cancer<br>Hospital<br>7- Sohag<br>Oncology<br>Center  |   |                       |   |
| 57- | 16/11/2022 | (ACTIV-<br>2D/A540<br>7) | Sponsor:<br>Shionogi<br>CRO:<br>IQVIA | A Phase 3,<br>Multicenter,<br>Randomized,<br>Double-Blind, 24-<br>Week Study of the<br>Clinical and<br>Antiviral Effect of<br>S-217622<br>Compared with<br>Placebo in Non-<br>Hospitalized<br>Participants with<br>COVID-19 | Interventional | III | 1-National<br>Hepatology and<br>Tropical<br>Medicine<br>Research<br>Institute<br>2-Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>(MASRI-CRC)<br>3-Alexandria<br>University<br>Clinical<br>Research<br>Center, 4-Air | Approved<br>31/1/2023<br><br>Withdrawn<br>26/9/2023 | Covid-19<br>treatment | (Pharmaceutical)<br><br>S-217622 /<br>matching<br>placebo |

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|     |            |              |   |  |                |     | Force<br>Specialized<br>Hospital<br>5-National<br>Institute for<br>Chest Allergy<br>and Diseases<br>6-Imbaba Fever<br>Hospital  |  |                        |  |
| 58- | 28/11/2022 | RBSC216<br>1 | Sponsor:<br>Salix<br>pharmace<br>uticals<br>CRO:<br>IQVIA | A Phase 2a<br>Randomized,<br>Double-Blind,<br>Placebo-<br>Controlled Study<br>to Characterize the<br>Pharmacokinetics<br>and<br>Pharmacodynamic<br>s of Rifaximin<br>Novel<br>Formulations in<br>Patients with<br>Sickle Cell<br>Disease | Interventional | Ila | 1-Cairo<br>University Abu<br>El Rich<br>Hospital.<br>2-Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>(MASRI-CRC)<br>3-Zagazig<br>University<br>Hospital<br>4-Cairo<br>University<br>Hospital<br>5-Alexandria<br>University | Approved<br>5/2/2023<br><br>Withdrawn<br>6/11/2023 | Sickle Cell<br>Disease | (Pharmaceutical)<br><br>Rifaximin /<br>matching<br>placebo |

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| Color<br>Indicator | Green  | Biological     |
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|                    | Orange | Medical Device |
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| 59- | 22/1/2023 | AT/03A-017 | Sponsor:<br>Atea<br>Pharmace<br>uti-cals<br><br>CRO:<br>Avicemer | A Phase 3<br>Randomized,<br>Double-Blind,<br>Placebo-<br>Controlled Study<br>to Evaluate the<br>Efficacy and<br>Safety of<br>Bemnifosbuvir in<br>High-Risk<br>Outpatients with<br>COVID-19 | Interventional | III | 1- National<br>Hepatology and<br>Tropical<br>Medicine<br>Research<br>Institute  | Approved:<br>15/10/2023<br><br>Withdrawn<br>7/4/2024 | COVID-19  | (Pharmaceutical)<br>Bemnifosbuvir/<br>matching<br>Placebo |
| 60- | 13/2/2023 | ENRICH-AF  | Sponsor:<br>Hamilton<br>Health<br>Science<br>CRO:<br>Clinmax     | Edoxaban for<br>Intracranial<br>Haemorrhage<br>Survivors with<br>Atrial Fibrillation<br>(ENRICH- AF)<br>Edoxaban<br>60/30mg once<br>daily  | Interventional | IV  | 1-Ain Shams<br>University<br>Clinical<br>Research Center<br>(MASRI-CRC)<br>2-Zagazig<br>University<br>Hospital<br>3-Fayoum<br>General<br>Hospital | Approved<br>10/5/2023<br><br>Recruiting              | Atrial<br>Fibrillation in<br>patients with<br>previous<br>Intracranial<br>Haemorrhage | (Pharmaceutical)<br>Edoxaban                              |

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|     |           |            |  |  |                |     | 4-Tanta<br>University<br>Hospital<br>5-Mansoura<br>University<br>Hospital<br>6-Ain Shams<br>Specialized<br>Hospital<br>7-Alexandria<br>University<br>Clinical<br>Research Center<br>8-Assuit<br>University<br>Hospital |  |                        |                                   |
| 61- | 13/2/2023 | GBT440-038 | Sponsor:<br>GBT<br>(Subsidiary of<br>Pfizer) | An Open-Label<br>Extension Study of<br>Voxelotor<br>Administered<br>Orally to<br>Paediatric<br>Participants with<br>Sickle Cell<br>Disease Who Have<br>Participated in | Interventional | III | 1-Alexandria<br>University<br>Clinical<br>Research<br>Center<br>2- Zagazig<br>University<br>Hospital<br>3-Cairo<br>University,   | Approved<br>30/3/2023<br><br>IMP Dosing<br>Pause<br>02/05/2024<br><br>Early<br>Terminated by | Sickle Cell<br>Disease | (Pharmaceutical)<br><br>Voxelotor |

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|     |          |                                  |                                     | Voxelotor Clinical Trials  |                |     | Abu El Rich Hospital.<br>4- Ain Shams University,<br>Faculty of Medicine CRC (MASRI). | the Sponsor<br>26/9/2024                            |                                    |   |
| 62- | 1/3/2023 | GN41851<br>FENHAN<br>CE          | Sponsor:<br>Roche<br>CRO: NA        | A Phase III Multicentre, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Teriflunomide In Adult Patients with Relapsing Multiple Sclerosis. | Interventional | III | 1-Alexandria University-Clinical Research Center                                      | Approved<br>26/4/2023<br><br>Withdrawn<br>11/1/2024 | Relapsing multiple sclerosis       | (Pharmaceutical)<br><br>Fenebrutinib/<br>Teriflunomide/<br>matching placebo |
| 63- | 6/3/2023 | 1305-0023<br>(FIBRONE<br>ER –ILD | Sponsor:<br>Boehringer<br>Ingelheim | A Double Blind, Randomized, Placebo-Controlled Trial   | Interventional | III | 1-Ain Shams University Clinical Research  | Approved<br>1/6/2023                                | Progressive Fibrosing Interstitial | (Pharmaceutical)  |

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|                 | Orange | Medical Device |
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|     |          |                                     | CRO:<br>IQVIA                     | Evaluating the Efficacy and Safety of BI 1015550 Over At Least 52 Weeks in Patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)                               |                |     | Center (MASRI-CRC)<br>2- Alexandria University Clinical Research Center<br>3- Air Force Specialized Hospital<br>4- Cairo University, Kasr Al Aini Hospital | Withdrawn<br>17/1/2024                              | lung diseases (PF-ILDs)             | BI 1015550 / matching placebo                         |
| 64- | 6/3/2023 | 1305-0014<br><br>(FIBRON EER – IPF) | Sponsor: Boehringer<br>CRO: IQVIA | A Double Blind, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of BI 1015550 Over At Least 52 Weeks in Patients with Idiopathic Pulmonary Fibrosis (IPF) | Interventional | III | 1- Ain Shams University Clinical Research Center (MASRI-CRC)<br>2- Alexandria University Clinical Research Center  | Approved<br>1/6/2023<br><br>Withdrawn<br>08/01/2024 | Idiopathic Pulmonary Fibrosis (IPF) | (Pharmaceutical)<br><br>BI 1015550 / matching placebo |

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|                 | Orange | Medical Device |
|                 | Gray   | Innovative     |
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|     |           |                           |  |  |                |     | 3- Air Force<br>Specialized<br>Hospital<br>4- Cairo<br>University,<br>Kasr Al Ainy<br>Hospital                         |   |   |  |
| 65- | 16/3/2023 | 4202-<br>HEM-201          | Sponsor:<br>Forma<br>Therapeut<br>ics<br>CRO:<br>MCT | A Phase 2 Open-<br>Label Study to<br>Evaluate Safety<br>and Clinical<br>Activity of FT-<br>4202 in Patients<br>with Thalassemia<br>or Sickle Cell<br>Disease | Interventional | II  | 1- Cairo<br>University,<br>Abu El-Rich<br>Children<br>Hospital.<br>2-Cairo<br>University,<br>Kasr Al Eini<br>Hospital. | Approved<br>1/6/2023<br><br>Recruiting              | Thalassemia<br>or Sickle Cell<br>Disease        | (Pharmaceutical)<br><br>Etavopivat                           |
| 66- | 15/5/2023 | EFC16035<br>(PERSEUS<br>) | Sponsor:<br>Sanofi<br>CRO: NA                        | A Phase 3,<br>Randomized,<br>Double-Blind,<br>Efficacy and<br>Safety Study<br>Comparing<br>SAR442168 to<br>Placebo in<br>Participants with<br>Primary        | Interventional | III | Alexandria<br>University<br>Clinical<br>Research<br>Center   | Approved<br>10/8/2023<br><br>Withdrawn<br>15/4/2024 | Primary<br>Progressive<br>Multiple<br>Sclerosis | (Pharmaceutical)<br><br>Tolebrutinib/<br>Matching<br>Placebo |

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| 67- | 14/3/2024 | WO43571<br>HereDER<br>A | Sponsor:<br>Roche<br>CRO: NA             | A Phase III,<br>Randomized,<br>Open-Label Study<br>Evaluating the<br>Efficacy and<br>Safety of<br>Giredestrant in<br>Combination with<br>Phesgo Versus<br>Phesgo After<br>Induction Therapy<br>with Phesgo+<br>Taxane in Patients<br>with Previously<br>Untreated Her2-<br>Positive, Estrogen<br>Receptor-Positive<br>Locally-Advanced<br>or Metastatic<br>Breast Cancer | Interventional | III | 1- Sohag<br>Oncology<br>Center<br>2- Dar El<br>Salam Cancer<br>Hospital<br>3- National<br>Cancer Institute | Approved<br>8/4/2024<br><br>Recruiting | Previously<br>Untreated<br>Her2-<br>Positive,<br>Estrogen<br>Receptor-<br>Positive<br>Locally-<br>Advanced or<br>Metastatic<br>Breast<br>Cancer | Pharmaceutical<br>Giredestrant |
| 68- | 22/4/2024 | 1517-CL-<br>1003        | Sponsor:<br>Astellas<br>Pharma<br>Global | A Phase 3, Open-<br>label,<br>Uncontrolled<br>Study to Evaluate  | Interventional | III | 1- Cairo<br>University<br>Children's<br>Hospital   | Approved<br>10/7/2024<br><br>Withdrawn | Anemia in<br>Pediatric<br>Patients with<br>Chronic  | Pharmaceutical<br>Roxadustat   |

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|                    | Orange | Medical Device |
|                    | Gray   | Innovative     |
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|     |          |         | Developm<br>ent<br>CRO:<br>MCT | the Activity,<br>Safety,<br>Pharmacokinetics<br>and<br>Pharmacodynamic<br>s of Roxadustat for<br>the Treatment of<br>Anemia in<br>Pediatric<br>Participants<br>with Chronic<br>Kidney Disease<br>1517-CL-1003 |                |     | 1- Ain Shams<br>University<br>Hospital<br>3- Alexandria<br>University<br>Hospital  | 26/9/2024            | Kidney<br>Disease                                    |                                |
| 69- | 5/6/2024 | M23-698 | Sponsor:<br>Abbvie<br>CRO: NA  | A Phase 3,<br>Randomized,<br>Placebo-<br>Controlled,<br>Double-Blind<br>Study to Evaluate<br>Efficacy and<br>Safety of<br>Upadacitinib in<br>Adult and<br>Adolescent<br>Subjects with<br>Moderate to          | Interventional | III | 1- Ain Shams<br>University<br>CRC (MASRI)<br>2- Air Force<br>Specialized<br>Hospital<br>3- Alexandria<br>University<br>CRC | Approved<br>7/8/2024 | Moderate to<br>Severe<br>Hidradenitis<br>Suppurativa | Pharmaceutical<br>Upadacitinib |

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|     |           |                   |  | Severe<br>Hidradenitis<br>Suppurativa Who<br>Have Failed Anti-<br>TNF Therapy<br>M23-698  |                |     |  |  |  |  |
| 70- | 24/7/2022 | MD-004            | Sponsor:<br>Ezz<br>Medical<br>Industries<br><br>CRO:Data<br>clin | Open labelled non<br>randomized self-<br>controlled study<br>to evaluate the<br>safety and<br>performance of<br>Ezvent in<br>hospitalized<br>mechanically<br>ventilated patients                          | Interventional | III | 1-Kasr Al-Aini<br>university<br>Hospital   | Approved<br>28/8/2022<br><br>Suspended<br>1-1-2024<br><br>Resuming<br>(ongoing)<br>13/1/2024 | Hospitalized<br>mechanically<br>ventilated<br>patients | Medical device<br>(Ezvent)   |
| 71- | 15/5/2022 | COAV10<br>1B12301 | Sponsor:<br>Novartis<br><br>CRO:<br>MCT                          | A randomized<br>sham controlled<br>double –blind<br>study to evaluate<br>the efficacy and<br>safety of<br>intrathecal (IT)<br>QAV101 in<br>patients with later<br>onset type 2 spinal<br>muscular atrophy | Interventional | III | 1-Department<br>of Neurology,<br>Ain Shams<br>University<br>Specialized<br>Hospital. | Approved<br>2-8-2022<br><br>Early<br>terminated<br>(by sponsor)<br>18-12-2023                | type 2 spinal<br>muscular<br>atrophy<br>(SMA)          | Innovative<br><br>QAV101<br>(Zolgensma)<br>(Onasemnogene<br>abeparvovec) |

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

|     |          |           |                                 |   |                |    |  |   |  |   |
|-----|----------|-----------|---------------------------------|---|----------------|----|--|---|--|---|
|     |          |           |                                 | (SMA) who are $\geq 2$ to <18 years of age, treatment naïve sitting and never ambulatory  |                |    |  |   |  |   |
| 72- | 6/6/2023 | Urso-003  | Sponsor: Minapharm              | 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 Chronic Liver Disease Patients | Interventional | IV | Clinical Research Center, Air force specialized Hospital -National Hepatology and Tropical Research Institute (NHTMRI) | Approved 18-9-2023<br><br>Suspended 26-11-2024<br><br>( Recruitment suspension) | Compensated Chronic Liver Disease Patients                 | Innovative<br><br>Ursoplus® capsules/<br>Ursofalk® capsules                 |
| 73- | 6/6/2023 | Cipro-001 | Sponsor: Minapharm,<br><br>CRO: | Single center, Open Label, controlled Study to assess the safety & efficacy of Oral Cipro Diazole ®   | Interventional | IV | 1- General Syrgery department, Menoufia University Hospital.   | Suspended 12-9-2023   | Pelvi-abdominal infections and following IV antibiotics in | Innovative<br><br>Cipro Diazole ® Tablets<br>(Ciprofolxacin/ Metronidazole) |

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

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|-----|-----------|----------------|-----------------------------------|---|----------------|----|---|---------------------|--|---|
|     |           |                | Nagy Research                     | Tablets (Ciprofolxacin/ Metronidazole) versus currently used Ciprofloxacin Tablets & Metronidazole tablets in pelvi-abdominal infections and following IV antibiotics in post-operative period, for pelvi-abdominal surgeries or acute conditions |                |    |   |                     | post-operative period, for pelvi-abdominal surgeries or acute conditions   |   |
| 74- | 15/5/2023 | Sub-Thromb-001 | Sponsor: Minapharm<br><br>CRO: NA | A Prospective, Single- Center, Phase IV Interventional, Single Arm Trial for the Evaluation of subcutaneous recombinant Hirudin 15 mg (RB variant) in   | Interventional | IV | 1- Department of Orthopedics and Trauma Surgery, El-Hadra University Hospital | Withdrawn 28-8-2023 | prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations | Innovative Thrombex (recombinant Hirudin) |

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

|     |            |                    |   |   |                |    |  |                                      |                        |  |
|-----|------------|--------------------|---|---|----------------|----|--|--------------------------------------|------------------------|--|
|     |            |                    |   | prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations  |                |    |  |                                      |                        |  |
| 75- | 24/10/2023 | GRC/NE-CV/EG/39/IV | Sponsor: Nerhadou International<br><br>CRO: Genuine research center | A prospective, Multicentre, Open-label, Single-arm Interventional Study of Bisoprolol (Nerkardou) (Between Low Dose and High Dose) 5 and 10 mg ODF Treatment In Egyptian Patients with Essential Hypertension | Interventional | IV | 1- Department of General Internal Medicine , Beni-Suef University Hospital<br>2- Department of Cardiology and vascular medicine , Fayoum University Hospital | Approved 10-3-2024<br><br>Recruiting | Essential Hypertension | Innovative<br><br>Nerkardou (Bisoprolol) Oral dispersible film |

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