

### 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-Withdrawn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<br>5-National<br>hepatology and | 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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|    |            |         |                   |                                                                                                                                                                                                                                                                                                                                           |                |     | 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 ;<br>or completed<br>M15-989 | 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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| 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<br>in subjects with<br>moderately to<br>severely active<br>ulcerative colitis.            | Interventional | III | 1- CRC, faculty<br>of medicine,<br>Alexandria<br>University<br>2-National<br>Liver Institute,<br>Menoufia<br>University<br>3-Air Force<br>Specialized<br>Hospital                                                      | 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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|    |           |                            |                   |                                                                                                                                                                                                                                                               |                |     | 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                  |
| 6- | 18/9/2019 | ARTEMI S-DM<br>“LPS1539 6” | SANOVI            | A multicenter, multinational, prospective, interventional, single-arm, Phase                                                                                                                                                                                  | Interventional | IV  | 1-Faculty of medicine, Alexandria university                                                | Approved<br>9/2/2020<br><br>Withdrawn | Type 2 diabetes mellitus      | (Biological)<br><br>Insulin glargine<br>“Toujeo” |

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|    |            |       |           | IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin                                               |                |    | 2-CRC, Alexandria university<br>3-GOTHI<br>4-Faculty of medicine, Menoufia university<br>5-Faculty of medicine, Ain Shams university |                                             |                    |                                   |
| 7- | 18/11/2019 | STAND | NOVART IS | A phase II, multicenter, randomized, open label, two arm study comparing the effect of crizanlizumab+ SOC alone on renal function in sickle cell disease patients $\geq 16$ years with chronic kidney disease due to sickle cell nephropathy | Interventional | II | 1-Abu El Resh Children Hospital                                                                                                      | Approved 5/5/2020<br><br>Withdrawn 3/8/2021 | Sickle cell anemia | (Biological)<br><br>Crizanlizumab |

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| 8- | 24/3/2020 | STEAD FAST | Sponsor: Novartis | A Phase III, multicenter, double-blind study to assess efficacy and safety of two doses of crizanlizumab vs placebo with or without hydroxyurea / hydroxycarbamide therapy, in adolescent and adult sickle cell disease patients with vaso-occlusive crisis | Interventional | III  | 1-Faculty of medicine, Alexandria university<br>2-Faculty of medicine, Ain Shams university                  | Approved 20/2/2020<br><br>Withdrawn 3/8/2021  | Sickle cell anemia                     | (Biological)<br><br>Crizanlizumab |
| 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                                                                                                     | 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   |

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|     |           |                               |                                                            | progressive<br>Multiple Sclerosis                                                                                                                                                                                                                     |                |     |                                                                                                                                                                        |                                                      |                                      |                                                                            |
| 10- | 14/9/2020 | 1368-0025                     | Boehringer<br>Ingelheim                                    | Open label long<br>term extension<br>study to assess the<br>safety and efficacy<br>of BI655130<br>treatment in<br>patients with<br>generalized<br>pustular psoriasis                                                                                  | Interventional | Iib | 1-Dermatology<br>department,<br>faculty of<br>medicine,<br>Alexandria<br>university<br>hospital                                                                        | Approved<br>18/5/2021<br><br>Withdrawn<br>31/10/2021 | Generalized<br>pustular<br>psoriasis | (Biological)<br><br>Spesolimab                                             |
| 11- | 21/9/2020 | 05-Gam-<br>COVID-<br>Vac-2020 | Sponsor:<br>Russian<br>Direct<br>Investment<br>Fund (RDIF) | A Phase III,<br>randomized,<br>double blind,<br>placebo-controlled<br>trial to evaluate<br>immunogenicity<br>and safety of the<br>Gam-COVID-Vac<br>combined vector<br>vaccine in<br>prophylactic<br>treatment for<br>SARS-COV-2<br>infection in Egypt | Interventional | III | 1-National liver<br>institute,<br>Menoufia<br>university<br>2-CRC, faculty<br>of medicine,<br>Alexandria<br>university<br>3- CRC,<br>MASRI, Ain<br>Shams<br>University | Withdrawn<br>12/6/2022                               | COVID-19<br>prophylaxis              | (Biological)<br><br>Russian Gam-<br>COVID-Vac<br>Combine vector<br>vaccine |
| 12- | 22/9/2020 | CNBG20<br>20003SQ             | China<br>National<br>Biotec                                | Multicenter,<br>Randomized,<br>Double blind,                                                                                                                                                                                                          | Interventional | III | 1-Vacsera<br>Health care<br>facility                                                                                                                                   | Approved<br>28/3/2022                                | COVID-19<br>Prophylaxis              | (Biological)                                                               |

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|     |           |                         | Group company limited Wuhan institute of biological products Co. Ltd Beijing institute of biological products Co.Ltd | parallel placebo controlled, Phase III clinical trial to evaluate the protective efficacy, safety and immunogenicity of Inactivated SARS-COV-2 Vaccines in healthy population aged 18 years old and above |                |     | 2-Ktameya medical center                                                                                                                         | Completed 31/7/2022                               |                                                                                                           | Inactivated SARS-COV-1 Vaccine              |
| 13- | 13/4/2021 | D910DC00001 (Emerald-2) | Sponsor: AstraZeneca<br>CRO: IQVIA                                                                                   | A phase 3 randomized double blind placebo controlled multicentre study of durvalumab monotherapy or in combination with bevacizumab as adjuvant therapy in patients with hepatocellular carcinoma who are | Interventional | III | 1-CRC, Faculty of medicine, Alexandria University hospital<br>2-National Liver Institute-Menoufia University<br>3-National Hepatology & Tropical | Approved 12/12/2021<br><br>Recruitment completion | Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation | (Biological)<br><br>Durvalumab\ Bevacizumab |

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|     |           |                       |                                                                                                          | at high risk of recurrence after curative hepatic resection or ablation                                                                                                                                                                                                   |                |     | Medicine Research Institute<br>4-Air Force specialized Hospital<br>5-Faculty of medicine, Assuit University |                                                               |                      |                                                  |
| 14- | 19/5/2021 | 01-Sputnik-Light-2021 | Sponsor:<br>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 |

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| 15- | 25/5/2021 | KATE-3            | Sponsor:<br>ROCHE    | A randomized, multi-center, double blind, placebo-controlled phase III study of the efficacy and safety of Trastuzumab Emtansine in combination with Atezolizumab or placebo in Pts with HER2-positive and PD-L1-positive locally advanced or metastatic breast cancer who have received prior Trastuzumab + Atezolizumab and Taxane- based therapy | Interventional | III | 1-Faculty of medicine, Kasr Al-Ainy hospital<br>2-Shefaa Al-Orman hospital<br>3-Baheya Hospital | Approved<br>5/12/2021<br><br>Withdrawn<br>19/12/2022 | HER2-positive and PD-L1-positive locally advanced or metastatic breast cancer | (Biological)<br><br>Trastuzumab Emtansine/<br>Atezolizumab |
| 16- | 27/5/2021 | CAIN457<br>P12301 | Sponsor:<br>Novartis | A randomized, double blind, placebo-controlled, parallel group, phase III                                                                                                                                                                                                                                                                           | Interventional | III | 1-CRC, Faculty of medicine, Alexandrian university                                              | Withdrawn<br>3/11/2021                               | Active ankylosing spondylitis                                                 | (Biological)<br><br>Secukinumab                            |

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|     |          |           |                               | multi-center study of intravenous Secukinumab to compare efficacy at 16 weeks with placebo and to assess safety and tolerability up to 52 weeks in subjects with active ankylosis spondylitis of non-radiographic axial spondylo arthritis |                |     |                                                                         |                     |                      |                                                                          |
| 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>Recruitment completion | Hepatocellular carcinoma | (Biological)<br>Atezolizumab/<br>Lenvatinib/<br>Sorafenib |
| 19- | 2/9/2021  | COVID_VACC_1 | Sponsor: National research center<br>CRO: CLINMAX | A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Inactivated SARS-CoV-2 Vaccine Against COVID-19 in Healthy Adults                                                       | Interventional | I   | National research center       | Approved 9/11/2021<br>Suspended 9/12/2021   | Covid-19 Prophylaxis     | (Biological)<br>Inactivated SARS-CoV-2 Vaccine            |
| 20- | 17/1/2022 | SPHINX-EGYPT | Sponsor:                                          | Safety and Immunogenicity                                                                                                                                                                                    | Interventional | I   | Al-Manial specialized          | Approved 3/2/2022                           | Covid-19 Prophylaxis     | (Biological)                                              |

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

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|     |          |             |                         |                                                                   |                |     | University hospital<br>4-CRC,<br>Alexandria University<br>5- Pediatric hematology department,<br>Alexandria University<br>6. CRC, faculty of medicine,<br>Cairo University,<br>Abo El-Resh Hospital<br>7- CRC, Cairo University<br>8- Hematology department,<br>Cairo University hospital |                    |                                         |                                |
| 22- | 4/1/2022 | GBT2104-132 | Global blood therapeuti | A Randomized, Double-blind, Placebo-controlled, Multicenter Study | Interventional | III | 1. Faculty of medicine, Mansoura University                                                                                                                                                                                                                                               | Approved 14/6/2022 | Sickle cell disease patients with Vaso- | (Biological)<br><br>Inclacumab |

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|  |  |  | cs Inc.\<br>Pfizer | 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) |  |  | 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,<br>Abo El-Resh<br>Hospital<br>7- CRC, Cairo<br>University | Withdrawn<br>29/6/2023 | occlusive<br>crisis |  |
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|     |            |             |                                                        |                                                                                                                                                                                          |                |     | 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 University hospital<br>5- Hematology department, Alexandria | Approved 14/6/2022<br><br>Withdrawn 17/12/2023 | sickle cell disease | (Biological)<br><br>Inclacumab/ Placebo |

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|     |          |                        |                                                                                                             |                                                                                                                                                      |                |     | 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 & IQVIA (for monitoring activities only) | 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 university hospital                          | Approved 20/9/2022<br><br>Recruitment completion | Progressive multiple sclerosis | (Biological)<br><br>Ocrelizumab |

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| 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>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>is Therapy for<br>ARDS A Phase<br>IIb/III<br>operationally<br>seamless, open-<br>label, randomized,<br>sequential,<br>parallel-group<br>adaptive study to<br>evaluate the<br>efficacy<br>and safety of daily<br>intravenous<br>alteplase treatment | Interventional | IIb/III | 1.National<br>Hepatology and<br>Tropical<br>Medicine<br>Research<br>Institute<br>2.Abbasia<br>Fever Hospital<br>3.Imbaba Fever<br>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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|     |           |                  |                                         | 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.                                                                                                            |                |     |                                                                                                                                            |                                                                 |                                               |                                 |
| 27- | 14/8/2022 | CAIN457<br>A2310 | Sponsor:<br>Novartis<br><br>CRO:<br>MCT | A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous Secukinumab compared to placebo and etanercept (in a single blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and | Interventional | III | 1-CRC, Faculty of Medicine, Alexandria university hospital<br>2-Dermatology department, faculty of Medicine, Ain Shams University hospital | 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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|     |           |                     |                                   | long-term efficacy in subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis                                                                                                                                                         |                |     |                                                                              |                                         |                                      |                                                                                                                |
| 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 previously unvaccinated with COVID-19 vaccine and aged ≥18 | 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) |
| 29- | 6/6/2023  | FUZION CNTO19 59CRD | Sponsor: Janssen<br>CRO:          | A Phase 3, Randomized, Placebo-controlled,                                                                                                                                                                                                                      | Interventional | III | 1.National Hepatology Tropical Medicine                                      | Approved<br>13/8/2023<br><br>Recruiting | Fistulizing perianal Crohn's disease | Guselkumab<br><br>(Biological)                                                                                 |

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|     |            |           | MCT                                                       | Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease "FUZION CD" |                |   | Research Institute<br>2.CRC, faculty of medicine Alexandria university hospital, (two sites)<br>3. Department of internal medicine, El Kasr Al Aini, Cairo University<br>4. MASRI CRC, faculty of medicine, Ain Shams University Hospital |                                     |                                             |                      |
| 30- | MP-ADA1-01 | 14/5/2023 | Sponsor: Minapharm<br>CRO: CRS Clinical Research Services | A Phase I, randomized, double-blind, 2-arm, parallel group trial to compare pharmacokinetics of Adessia with EU-authorized                                 | Interventional | I | -CRS clinical research services, Berlin GmbH<br>-CRS clinical research services,                                                                                                                                                          | Approved 10/8/2023<br><br>Completed | Inflammatory disease (Biosimilar to Humira) | Adessia (Biological) |

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|     |          |              | Berlin GmbH                      | Humira in healthy male and female participants”                                                                                                                                       |                |        | Mannheim GmbH                                                                                                                                                                                                                                                                                                                |                                                                      |                                  |                   |
| 31- | 4/5/2023 | MOM-M281-006 | Sponsor: Janssen<br><br>CRO: MCT | Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a Long-term Open-label Extension” | Interventional | II/III | -National Cancer Institute, Cairo university<br>-Oncology center, Mansoura University Hospital<br>-Department of internal medicine, Al Kasr al Eini, Cairo university<br>-Naser institute hospital for research and treatment<br>-CRC, faculty of medicine, Alexandria university Hospital<br>-CRC, faculty of medicine, Ain | Approved 19/7/2023<br><br>Early Terminated by the sponsor 21/02/2025 | Warm Autoimmune Hemolytic Anemia | M281 (Biological) |

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|     |                                                                    |                                   |                                               |                                                                                                                                                                                                                                                                                                                                                       |                |     | 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<br>(TACE) Compared<br>to TACE Alone in<br>Patients with<br>Locoregional<br>Hepatocellular<br>Carcinoma<br>(EMERALD-3) | 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<br>Research<br>Institute<br>(NHTMRI)<br>- Shifa El<br>orman Hospital | Approved<br>8/2/2024<br><br>Recruiting | Locoregional<br>Hepatocellular<br>Carcinoma | (Biological)<br><br>Durvalumab /<br>Tremelimumab/<br>Lenvatinib /TACE   |
| 33- | not<br>submitted<br>officially                                     | CERE-<br>CAP                      | investigat<br>or-<br>initiated                | Efficacy of<br>Cerebrolysin as an<br>adjuvant therapy<br>following<br>mechanical                                                                                                                                                                                                                                                                      | Interventional | III | Neurology and<br>psychiatry<br>department,<br>Ain Shams                                                                                                                                                                                                                        | Terminated<br>(by EDA)<br>(15/1/2024)  | occlusion<br>stroke                         | (Biological)<br>CEREBROLY<br>SIN solution<br>for IM or IV<br>injection/ |

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|     |            |              |                                                   | thrombectomy in patients with large vessels occlusion stroke                                                                                                                              |                |     | University Hospital                                                                   |                                                                                                       |                                                          | concentrate for solution for I.V. infusion |
| 34- | 14/12/2023 | BCD-178      | Sponsor:<br>JSC<br>BIOCAD<br><br>CRO:<br>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:<br>22/4/2024                                                                                | Her-2 positive breast cancer                             | Biological<br><br>BCD-178                  |
| 35- | 8/1/2024   | SerpinPc 102 | Sponsor:<br>Apcintex<br><br>CRO:<br>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<br>13/6/2024<br><br>Final Approval<br>31/10/2024<br><br>Withdrawn:<br>16/01/2025 | Hemophilia A or Moderately Severe to Severe Hemophilia B | Biological<br><br>SerpinPC 102             |

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| 36- | 8/1/2024 | SerpinPC<br>103             | Sponsor:<br>Apcintex<br><br>CRO:<br>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<br>13/6/2024<br><br>Final Approval<br>31/10/2024<br><br>Withdrawn:<br>16/01/2025 | Hemophilia B with Inhibitors                   | Biological<br><br>Serpin PC 103 |
| 37- | 8/2/2024 | D9185C00<br>001''TILI<br>A' | Sponsor:<br>AstraZenca<br>CRO:<br>IQIVIA | A Phase III, Multicenter, Randomized, Double-bind, Parallel-group, Placebo-Controlled study to evaluate the efficacy and safety of Tozoralimab (MEDI3506) in patients hospitalized for viral lung infection requiring supplemental oxygen | Interventional | III | 1-Air Force specialized Hospital<br>2-Ain Shams University Medical research Institute (MASRI-CRC)<br>3-CRC, Alexandria University Hospital | Approved:<br>4/8/2024<br><br>Withdrawn :<br>30/01/2025                                                | Patients hospitalized for viral lung infection | Biological<br><br>Tozoralimab   |

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| 38- | 16/01/2025 | GA45329-<br>Ametrine<br>1 | Sponsor:<br>Roche<br>CRO: NA | A Phase III,<br>Multicenter,<br>Double-Blind,<br>Placebo-<br>Controlled, Treat-<br>Through Study to<br>Assess the<br>Efficacy and<br>Safety of<br>Induction and<br>Maintenance<br>Therapy With<br>RO7790121 In<br>Patients with<br>Moderately to<br>Severely Active<br>Ulcerative Colitis | Interventional | III | Clinical<br>Research<br>Center, Internal<br>Medicine<br>Faculty of<br>Medicine,<br>Alexandria<br>University | Approved:<br>10/03/2025 | Patients with<br>Moderately<br>to Severely<br>Active<br>Ulcerative<br>Colitis | Biological<br><br>RO7790121 |
| 39- | 16/01/2025 | GA45330-<br>Ametrine<br>2 | Sponsor:<br>Roche<br>CRO: NA | A Phase III,<br>Multicenter,<br>Double-Blind,<br>Placebo-<br>Controlled Study<br>to Assess the<br>Efficacy and<br>Safety of<br>Induction Therapy<br>with RO7790121<br>In Patients with                                                                                                    | Interventional | III | Clinical<br>Research<br>Center, Internal<br>Medicine<br>Faculty of<br>Medicine,<br>Alexandria<br>University | Approved:<br>10/03/2025 | Patients with<br>Moderately<br>to Severely<br>Active<br>Ulcerative<br>Colitis | Biological<br><br>RO7790121 |

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|     |            |                             |                               | Moderately to Severely Active Ulcerative Colitis                                                                                                                                                                             |                |    |                                                                                                                                                         |                                               |                              |                                                                                   |
| 40- | 17/12/2020 | CEGA23 0B2404               | Sponsor: Novartis<br>CRO: MCT | A Phase IV Multicenter Open Label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of Egaten (Triclabandazole) in Patients 6 Years of Age or Older with Fascioliasis (Egaten) | Interventional | IV | 1-Cairo University, Al Mounira Children Hospital, Pediatric Hepatology Unit.<br>2-Alexandria University, Faculty of Medicine, Clinical Research Center. | Approved 12/4/2021<br><br>Recruiting          | Fascioliasis                 | (Pharmaceutical)<br><br>Triclabandazole (Egaten)                                  |
| 41- | 22/12/2020 | CLEE011 A3201C RIGHT Choice | Sponsor: Novartis<br>CRO: MCT | A Phase II Randomized Study of the Combination of Ribociclib Plus Goserelin Acetate with Hormonal Therapy Versus Physician Choice Chemotherapy in                                                                            | Interventional | II | 1-Ain Shams University, Faculty of Medicine, Clinical Research Center, (MASRI – CRC)                                                                    | Approved 14/10/2021<br><br>Completed 8/1/2023 | HER-2 Negative Breast Cancer | (Pharmaceutical)<br><br>Ribociclib Plus Goserelin / Physician Choice Chemotherapy |

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|     |            |         |                            | Premenopausal or Perimenopausal Patients with Hormone Receptor-Positive/HER2-Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study                                        |                |     | 2-Baheya Hospital Research Center<br>3-Cairo University, NEMROCK<br>4-Nasser Institute Cancer Center                                                                                                 |                                                 |                 |                                                        |
| 42- | 24/10/2021 | M14-430 | Sponsor: Abbvie<br>CRO: NA | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease Who Completed | Interventional | III | 1-Air Force Specialized Hospital<br>2-National Liver Institute Menoufiya University<br>3-Alexandria University, Faculty of Medicine, Clinical Research Center.<br>4-Ain Shams University, Faculty of | Approved 7/7/2022<br><br>Recruitment Completion | Chron's Disease | (Pharmaceutical)<br><br>Upadacitinib/ matching placebo |

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|     |            |                                       |                              | the Studies M14-431 or M14-433                                                                                                                                                                                                                                                                  |                |     | Medicine, Clinical Research Center (MASRI-CRC).                                       |                                                     |                                   |                                                                       |
| 43- | 26/10/2021 | BO40336<br>ALINA                      | Sponsor:<br>Roche<br>CRO: NA | A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors $\geq$ 4 Cm) To Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer | Interventional | III | 1- Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine. | Approved<br>16/3/2022<br><br>Recruitment Completion | Lung Cancer                       | (Pharmaceutical)<br><br>Alectinib /<br>Platinum based<br>Chemotherapy |
| 44- | 12/12/2021 | Cl_Tr_17<br>122019<br>MIRACL<br>E-ALA | Sponsor:<br>EVA<br>Pharma    | A Multicenter, Interventional, Two-Arm, Parallel-Group,                                                                                                                                                                                                                                         | Interventional | IV  | 1- Alexandria University Hospital, Diabetes,                                          | Approved<br>12/10/2022                              | Treatment of Symptomatic Diabetic | (Pharmaceutical)<br><br>Alpha-Lipoic Acid                             |

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|     |            |                                  | CRO:<br>MARC               | Randomized,<br>Double-Blinded,<br>Placebo-<br>Controlled, Phase<br>IV Trial to<br>Evaluate the<br>Efficacy of Alpha-<br>Lipoic Acid in the<br>Treatment of<br>Patients with<br>Symptomatic<br>Diabetic<br>Polyneuropathy in<br>Egypt |                |     | Metabolism, and<br>Lipidology Unit,<br>Department of<br>Internal<br>Medicine.<br>2- Ain<br>Shams<br>University<br>Hospital<br>3- Menoufi<br>ya University<br>Hospital<br>4- Mansour<br>a University,<br>Intrinsic<br>Specialized<br>Hospital.<br>5- Beni-<br>Suef University<br>Hospital,<br>Diabetes and<br>Endocrinology<br>Unit. | Completed<br>11/12/2024 | Polyneuropat<br>hy             | (Thiotacid)/<br>matching<br>placebo                          |
| 45- | 12/12/2021 | MK4482-<br>013<br>MOVE-<br>Ahead | Sponsor:<br>MSD<br>CRO: NA | A Phase 3<br>Multicenter,<br>Randomized,<br>Double Blind,<br>Placebo                                                                                                                                                                 | Interventional | III | 1-Ain Shams<br>University<br>Clinical<br>Research<br>Center                                                                                                                                                                                                                                                                         | Approved<br>18/1/2022   | Prophylaxis<br>of COVID-<br>19 | (Pharmaceutical)<br><br>Molnupiravir/<br>matching<br>placebo |

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|     |           |            |                                              | 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. |                |     | (MASRI-CRC).<br>2-Air Force Specialized Hospital.<br>3-National Hepatology and Tropical Medicine Research Institute.<br>4-Imbaba Fever Hospital.<br>5-National Center for Allergies and Chest Imbaba | Completed<br>16/11/2022                                                                         |                     |                                                        |
| 46- | 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 Sick Cell                                        | Interventional | III | 1-Ain Shams University Clinical Research Center (MASRI-CRC).<br>2-Alexandria University Clinical                                                                                                     | Approved<br>31/7/2022<br><br>IMP Dosing Pause<br>02/05/2024<br>Early Termination by the sponsor | Sickle Cell Disease | (Pharmaceutical)<br><br>Voxelotor/<br>matching placebo |

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|     |           |            |                                                   | Disease (HOPE Kids 2)                                                                                                                            |                |     | Research Center.<br>3- Al Mounira Children Hospital, Cairo University,<br>4-Zagazig University Hospital, Department of Pediatrics.                                                   | 29/09/2024                                                                  |                     |                                   |
| 47- | 18/4/2022 | GBT440-034 | Sponsor: GBT (Subsidiary of Pfizer)<br>CRO: IQVIA | An Open Label Extension Study of GBT440 Administered Orally to Patients with Sickel Cell Disease who Have Participated in GBT440 Clinical Trials | Interventional | III | 1-Cairo University, 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 | Approved 2/8/2022<br><br>Early Termination by the sponsor<br><br>30/09/2024 | Sickle Cell Disease | (Pharmaceutical)<br><br>Voxelotor |

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| Orange | Medical Device |
| Gray   | Innovative     |
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|     |           |                  |                                  |                                                                                                                                                                                                                                                                              |                |     | Hospital,<br>Department of<br>Pediatrics.                                                                                                                                                                                                                                                                                              |                                         |                                 |                                  |
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| 48- | 17/5/2022 | F901318/<br>0032 | Sponsor:<br>F2G<br>CRO:<br>IQVIA | Open Label Single<br>Arm Phase IIb<br>Study of F901318<br>as Treatment of<br>Invasive Fungal<br>Infections Due to<br>Lomentospora<br>Prolificans,<br>Seedosporium<br>Spp., Aspengillus<br>Spp., & other<br>Resistant Fungi in<br>Patients Lacking<br>Suitable<br>Alternative | Interventional | IIb | 1-Mansoura<br>University<br>Oncology<br>center<br>2-Alexandria<br>University,<br>Clinical<br>Research<br>Center<br>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 | Terminated<br>(By Sponsor)<br>24/7/2022 | Invasive<br>Fungal<br>Infection | (Pharmaceutical)<br><br>Olorofim |

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|     |           |                                 |                                                                                          |                                                                                                                                                                                                                                              |                |        | Al-Eini,<br>Hospital                                                                                                                                                                                                           |                                                      |                                                                  |                                                                               |
| 49- | 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<br>– Organization to<br>Assess Strategies<br>for Ischemic<br>Syndromes 9 | Interventional | III/IV | 1-Mansoura<br>University<br>Hospital<br>2-Suez Canal<br>University<br>Hospital<br>3-Fayoum<br>General<br>Hospital<br>4-Tamia<br>Central<br>Hospital<br>5-El Kharga<br>Specialized<br>Hospital<br>6-National<br>Heart Institute | 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 |
| 50- | 15/6/2022 | 20140106                        | Sponsor:<br>Onyx<br>Pharmace<br>uticals<br>(Subsidiar<br>y of<br>Amgen)<br>CRO:<br>IQVIA | Phase 1b/2 Study<br>of Carfilzomib in<br>Combination with<br>Induction<br>Chemotherapy in<br>Children with<br>Relapsed or<br>Refractory Acute                                                                                                | Interventional | Ib/II  | 1-Children's<br>Cancer<br>Hospital 57357                                                                                                                                                                                       | Approved<br>23/8/2022<br><br>Withdrawn<br>19/6/2023  | Relapsed or<br>Refractory<br>Acute<br>Lymphoplasti<br>c Leukemia | (Pharmaceutical)<br><br>Carfilzomib                                           |

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|     |           |              |                            | Lymphoblastic Leukemia                                                                                                                                             |                |        |                                                                                                                                                                                                                   |                                               |                                                       |                                                      |
| 51- | 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 Mitapivat in Subjects with Sickle Cell Disease | Interventional | II/III | 1-Alexandria University Clinical Research Center<br>2-Zagazig University Hospital<br>3-Cairo University Hospital<br>4-Mansoura University Hospital<br>5-Ain Shams University Clinical Research Center (MASRI-CRC) | Approved 27/9/2022<br><br>Withdrawn 21/8/2023 | Sickle Cell Disease                                   | (Pharmaceutical)<br><br>Mitapivat / matching placebo |
| 52- | 26/7/2022 | F901318/0041 | Sponsor: F2G<br>CRO: IQVIA | A Phase III, Adjudicator-Blinded, Randomised Study to Evaluate the Efficacy and                                                                                    | Interventional | III    | 1-Mansoura University Oncology Center<br>2-Alexandria University                                                                                                                                                  | Approved 11/10/2022                           | Invasive Fungal Disease caused by Aspergillus species | (Pharmaceutical)<br><br>Olorofim / Ambisome          |

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|     |           |            |                         | Safety of Treatment with Olorofim Versus Treatment with Ambisome® Followed by Standard of Care (SOC) in Patients with Invasive Fungal Disease (IFD) Caused by Aspergillus Species |                |     | Clinical Research Center 3-Air Force specialized Hospital 4-Ain Shams University, Clinical 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 |                    |                             |                  |
| 53- | 27/7/2022 | APD334-202 | Sponsor: Arena Pharmace | A Multicenter Randomized Double Blinded                                                                                                                                           | Interventional | III | 1-Alexandria University Clinical                                                                                                                                                                                                                                        | Approved 23/8/2022 | Moderately to Severe Active | (Pharmaceutical) |

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|  |  |  | uticals<br>(Subsidiar<br>y of<br>Pfizer) | Parallel Group<br>Study to Assess<br>the Efficacy and<br>Safety of Oral<br>Etrasimod as<br>Induction and<br>Maintenance<br>Therapy for<br>Moderately to<br>Severe Active<br>Crohn's Disease<br>(Etrasimod) |  |  | Research<br>Center<br>2-Air Force<br>Specialized<br>Hospital<br>3-National<br>Liver Institute<br>4-National<br>Hepatology and<br>Tropical<br>Medicine<br>Research<br>Institute<br>(NHTMRI)<br>4-Cairo<br>University Kasr<br>Al-Eini<br>Hospital<br>5-Egyptian<br>Liver Research<br>Institute and<br>Hospital<br>6-Ain Shams<br>University<br>Hospital<br>7-Theodor<br>Bilharz | Recruitment<br>Completion<br><br>Early<br>Terminated by<br>the sponsor<br>20/03/2025 | Crohn's<br>Disease | Etrasimod /<br>matching<br>placebo |
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| 54- | 7/8/2022  | EFC1721<br>5<br>LEAP-2-<br>MONO | Sponsor:<br>Sanofi<br>CRO: NA    | A Phase 3,<br>Multicenter,<br>Multinational<br>Randomized<br>Double-Blind<br>Double-Dummy,<br>Active<br>Comparator Study<br>to Evaluate the<br>Efficacy and<br>Safety of<br>Venglustat in<br>Adult and<br>Pediatric Patients<br>with Gaucher<br>Disease Type 3<br>(GD3) who Have<br>Reached<br>Therapeutic Goals<br>with Enzyme<br>Replacement<br>Therapy | Interventional | III | 1-Alexandria<br>University<br>Hospital<br>Clinical<br>Research<br>Center | Approved<br>24/10/2022 | Gaucher<br>Disease Type<br>3 (GD3)            | (Pharmaceutical)<br><br>Venglustat/<br>Cerezyme |
| 55- | 15/8/2022 | AG348-<br>C-017                 | Sponsor:<br>Agios<br>CRO:<br>MCT | A Phase 3,<br>Double-blind,<br>Randomized,<br>Placebo-                                                                                                                                                                                                                                                                                                    | Interventional | III | 1-Cairo<br>University<br>Hospital                                        | Approved<br>2/11/2022  | Non-<br>Transfusion-<br>Dependent<br>Alpha or | (Pharmaceutical)<br><br>Mitapivat /             |

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|                    | Orange | Medical Device |
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|     |           |                 |                                  | Controlled,<br>Multicenter Study<br>Evaluating the<br>Efficacy and<br>Safety of<br>Mitapivat in<br>Subjects with<br>Non–Transfusion-<br>Dependent Alpha-<br>or Beta-<br>Thalassemia<br>(ENERGIZE)                                                         |                |     | 2-Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>MASRI-CRC                                          | Withdrawn<br>26/6/2023                              | Beta<br>Thalassemia                                          | matching<br>placebo                                        |
| 56- | 15/8/2022 | AG348-<br>C-018 | Sponsor:<br>Agios<br>CRO:<br>MCT | A Phase 3,<br>Double-blind,<br>Randomized,<br>Placebo-<br>Controlled,<br>Multicenter Study<br>Evaluating the<br>Efficacy and<br>Safety of<br>Mitapivat in<br>Subjects with<br>Transfusion-<br>Dependent Alpha-<br>or Beta-<br>Thalassemia<br>(ENERGIZE-T) | Interventional | III | 1-Cairo<br>University<br>Hospital<br><br>2-Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>MASRI-CRC | Approved<br>2/11/2022<br><br>Withdrawn<br>26/6/2023 | Transfusion-<br>Dependent<br>Alpha or<br>Beta<br>Thalassemia | (Pharmaceutical)<br><br>Mitapivat /<br>matching<br>placebo |

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| 57- | 29/8/2022 | 4202-<br>HEM-301  | Sponsor:<br>Forma<br>Therapeut<br>ics<br>CRO:<br>MCT | An Adaptive,<br>Randomized,<br>Placebo-<br>Controlled,<br>Double-blind,<br>Multi-center Study<br>of Oral<br>Etavopivat, a<br>Pyruvate Kinase<br>Activator in<br>Patients with<br>Sickle Cell<br>Disease | Interventional | III | 1- Alexandria<br>University<br>Clinical<br>Research<br>Center<br>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) | Approved<br>11/12/2022<br><br>Recruitment<br>Completion | Sickle Cell<br>Disease                                                                | (Pharmaceutical)<br><br>Etavopivat /<br>matching<br>placebo                                              |
| 58- | 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           | 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                                                                       | Approved<br>4/12/2022<br><br>Recruitment<br>Completion  | Estrogen<br>Receptor<br>-Positive<br>, Her2-<br>Negative<br>Early<br>Breast<br>Cancer | (Pharmaceutical)<br><br>Giredestrant /<br>Physician<br>Choice of<br>Adjuvant<br>Endocrine<br>Monotherapy |

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|     |            |                          |                                       | Endocrine<br>Monotherapy in<br>Patients with<br>Estrogen<br>Receptor-Positive,<br>Her2-Negative<br>Early Breast<br>Cancer                                                                                                   |                |     | 4-Cairo<br>University Kasr<br>Al- Ainy<br>Hospital<br>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       |                                                     |                       |                                                           |
| 59- | 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 | 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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|     |            |              |                                                           |                                                                                                                                                                                                                                          |                |     | Clinical<br>Research<br>Center, 4-Air<br>Force<br>Specialized<br>Hospital<br>5-National<br>Institute for<br>Chest Allergy<br>and Diseases<br>6-Imbaba Fever<br>Hospital                                     |                                                    |                        |                                                            |
| 60- | 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 | 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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|     |           |            |                                                     |                                                                                                                                                          |                |     | 5-Alexandria University Clinical Research Center                                                                          |                                                  |                                                                        |                                                  |
| 61- | 22/1/2023 | AT/03A-017 | Sponsor: Atea Pharmaceuti-cals<br><br>CRO: Avicemer | A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Bemnifosbuvir in High-Risk Outpatients with COVID-19 | Interventional | III | 1- National Hepatology and Tropical Medicine Research Institute                                                           | Approved: 15/10/2023<br><br>Withdrawn 7/4/2024   | COVID-19                                                               | (Pharmaceutical) Bemnifosbuvir/ matching Placebo |
| 62- | 13/2/2023 | ENRICH-AF  | Sponsor: Hamilton Health Science<br>CRO: Clinmax    | Edoxaban for Intracranial Haemorrhage Survivors with Atrial Fibrillation (ENRICH- AF)<br>Edoxaban 60/30mg once daily                                     | Interventional | IV  | 1-Ain Shams University Clinical Research Center (MASRI-CRC)<br>2-Zagazig University Hospital<br>3-Fayoum General Hospital | Approved 10/5/2023<br><br>Recruitment Completion | Atrial Fibrillation in patients with previous Intracranial Haemorrhage | (Pharmaceutical) 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 |                                                                                              |                        |                                   |
| 63- | 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                            |                                                             |                                                                             |
| 64- | 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 |
| 65- | 6/3/2023 | 1305-0023<br>(FIBRONE<br>ER –ILD | Sponsor:<br>Boehringer<br>Ingelheim | A Double Blind, Randomized, Placebo-Controlled Trial Evaluating the                                                                                                                                                        | Interventional | III | 1-Ain Shams University Clinical Research                                              | Approved<br>1/6/2023<br><br>Withdrawn               | Progressive Fibrosing Interstitial lung diseases (PF- ILDs) | (Pharmaceutical)<br><br>BI 1015550 /<br>matching placebo                    |

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|     |          |                                               | CRO:<br>IQVIA                                             | Efficacy and<br>Safety of BI<br>1015550 Over At<br>Least 52 Weeks in<br>Patients with<br>Progressive<br>Fibrosing<br>Interstitial Lung<br>Diseases (PF-<br>ILDs)                                                       |                |     | Center<br>(MASRI-CRC)<br>2- Alexandria<br>University<br>Clinical<br>Research<br>Center<br>3- Air Force<br>Specialized<br>Hospital<br>4- Cairo<br>University,<br>Kasr Al Aini<br>Hospital | 17/1/2024                                           |                                              |                                                             |
| 66- | 6/3/2023 | 1305-<br>0014<br><br>(FIBRON<br>EER –<br>IPF) | Sponsor:<br>Boehringer<br>r<br>Ingelheim<br>CRO:<br>IQVIA | A Double Blind,<br>Randomized,<br>Placebo-<br>Controlled Trial<br>Evaluating the<br>Efficacy and<br>Safety of BI<br>1015550 Over At<br>Least 52 Weeks in<br>Patients with<br>Idiopathic<br>Pulmonary<br>Fibrosis (IPF) | Interventional | III | 1- Ain Shams<br>University<br>Clinical<br>Research<br>Center<br>(MASRI-CRC)<br>2- Alexandria<br>University<br>Clinical<br>Research<br>Center<br>3- Air Force<br>Specialized<br>Hospital  | Approved<br>1/6/2023<br><br>Withdrawn<br>08/01/2024 | Idiopathic<br>Pulmonary<br>Fibrosis<br>(IPF) | (Pharmaceutical)<br><br>BI 1015550 /<br>matching<br>placebo |

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|     |           |                    |                                         |                                                                                                                                                           |                |     | 4- Cairo University, Kasr Al Ainy Hospital                                                        |                                               |                                        |                                                           |
| 67- | 16/3/2023 | 4202-HEM-201       | Sponsor: Forma Therapeutics<br>CRO: MCT | A Phase 2 Open-Label Study to Evaluate Safety and Clinical Activity of FT-4202 in Patients with Thalassemia or Sickle Cell Disease                        | Interventional | II  | 1- Cairo University, Abu El-Rich Children Hospital.<br>2-Cairo University, Kasr Al Eini Hospital. | Approved 1/6/2023<br><br>Recruiting           | Thalassemia or Sickle Cell Disease     | (Pharmaceutical)<br><br>Etavopivat                        |
| 68- | 15/5/2023 | EFC16035 (PERSEUS) | Sponsor: Sanofi<br>CRO: NA              | A Phase 3, Randomized, Double-Blind, Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis | Interventional | III | Alexandria University Clinical Research Center                                                    | Approved 10/8/2023<br><br>Withdrawn 15/4/2024 | Primary Progressive Multiple Sclerosis | (Pharmaceutical)<br><br>Tolebrutinib/<br>Matching Placebo |

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| Blue   | Pharmaceutical |
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| 69- | 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 |
| 70- | 22/4/2024 | 1517-CL-<br>1003        | Sponsor:<br>Astellas<br>Pharma<br>Global Developm<br>ent<br>CRO:<br>MCT | A Phase 3, Open-<br>label,<br>Uncontrolled<br>Study to Evaluate<br>the Activity,<br>Safety,<br>Pharmacokinetics<br>and                                                                                                                                                                                                                                                   | Interventional | III | 1- Cairo<br>University<br>Children's<br>Hospital<br>1- Ain Shams<br>University<br>Hospital                 | Approved<br>10/7/2024<br><br>Withdrawn<br>26/9/2024 | Anemia in<br>Pediatric<br>Patients with<br>Chronic<br>Kidney<br>Disease                                                                         | Pharmaceutical<br>Roxadustat   |

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| Color<br>Indicator | Green  | Biological     |
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|     |            |                |                               | 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                                                                                                                                     |                |     | 3- Alexandria<br>University<br>Hospital                                                                                    |                        |                                                      |                                |
| 71- | 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 Safety<br>of Upadacitinib in<br>Adult and<br>Adolescent<br>Subjects with<br>Moderate to Severe<br>Hidradenitis<br>Suppurativa Who<br>Have Failed Anti-<br>TNF Therapy<br>M23-698 | 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 |
| 72- | 16/12/2024 | DAY101-<br>002 | Sponsor:<br>Day One           | A Phase 3,<br>Randomized,<br>International                                                                                                                                                                                                                                                 | Interventional | III | • Children<br>Cancer                                                                                                       | Approved<br>20/02/2025 | Pediatric<br>Low-Grade                               | Pharmaceutical<br>Tovorafenib  |

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|     |           |                | Biopharmaceuticals                               | Multicenter Trial of DAY101 Monotherapy Versus Standard of Care Chemotherapy in Patients with Pediatric Low-Grade Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy |                |     | Hospital Egypt-57357                                                  |                                                                          | Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy |                                                          |
| 73- | 24/7/2022 | MD-004         | Sponsor: Ezz Medical Industries<br>CRO:Data clin | Open labelled non randomized self-controlled study to evaluate the safety and performance of Ezvent in hospitalized mechanically ventilated patients                                                  | Interventional | III | 1-Kasr Al-Aini university Hospital                                    | Approved 28/8/2022<br>Suspended 1-1-2024<br>Resuming (ongoing) 13/1/2024 | Hospitalized mechanically ventilated patients                                       | Medical device (Ezvent)                                  |
| 74- | 15/5/2022 | COAV10 1B12301 | Sponsor: Novartis<br>CRO: MCT                    | A randomized sham controlled double –blind study to evaluate the efficacy and safety of                                                                                                               | Interventional | III | 1-Department of Neurology, Ain Shams University Specialized Hospital. | Approved 2-8-2022<br>Early terminated (by sponsor)                       | type 2 spinal muscular atrophy (SMA)                                                | Innovative QAV101 (Zolgensma) (Onasemnogene abeparvovec) |

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|     |          |           |                                               | intrathecal (IT)<br>QAV101 in<br>patients with later<br>onset type 2 spinal<br>muscular atrophy<br>(SMA) who are $\geq 2$<br>to <18 years of<br>age, treatment<br>naïve sitting and<br>never ambulatory                                                                |                |    |                                                                                                                                                         | 18-12-2023                                                                               |                                                     |                                                                   |
| 75- | 6/6/2023 | Urso-003  | Sponsor:<br>Minapharm<br><br>CRO:<br>Dataclin | Multi-Center,<br>randomized,<br>control, phase IV<br>trial to compare<br>the efficacy &<br>safety of<br>Ursoplus®<br>capsules (UDCA<br>250mg &<br>Silymarin 140mg)<br>versus UDCA<br>alone versus<br>Placebo among<br>Compensated<br>Chronic Liver<br>Disease Patients | Interventional | IV | Clinical<br>Research<br>Center, Air<br>force<br>specialized<br>Hospital<br>-National<br>Hepatology and<br>Tropical<br>Research<br>Institute<br>(NHTMRI) | Approved<br>18-9-2023<br><br>Suspended<br>26-11-2024<br><br>( Recruitment<br>suspension) | Compensated<br>Chronic<br>Liver Disease<br>Patients | Innovative<br><br>Ursoplus®<br>capsules/<br>Ursofalk®<br>capsules |
| 76- | 6/6/2023 | Cipro-001 | Sponsor:                                      | Single center,<br>Open Label,                                                                                                                                                                                                                                          | Interventional | IV | 1- General<br>Surgery                                                                                                                                   | Suspended                                                                                | Pelvi-<br>abdominal                                 | Innovative                                                        |

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|     |           |                | Minapharm,<br><br>CRO:<br>Nagy Research | controlled Study to assess the safety & efficacy of Oral Ciprofloxacin 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 |                |    | department, Menoufia University Hospital.                                     | 12-9-2023           | infections and following IV antibiotics in post-operative period, for pelvi-abdominal surgeries or acute conditions | Ciprofloxacin® Tablets (Ciprofolxacin/ Metronidazole) |
| 77- | 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                                                                                                                                                                                                               | 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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|     |            |                            |                                                                                         | recombinant<br>Hirudin 15 mg<br>(RB variant) in<br>prophylaxis of<br>Deep Vein<br>Thrombosis<br>(DVT) post major<br>orthopedic<br>operations                                                                                                          |                |    |                                                                                                                                                                                                  |                                         |                           |                                                                         |
| 78- | 24/10/2023 | GRC/NE-<br>CV/EG/3<br>9/IV | Sponsor:<br>Nerhadou<br>Internatio-<br>nal<br><br>CRO:<br>Genuine<br>research<br>center | A prospective,<br>Multicentre, Open-<br>label, Single-arm<br>Interventional<br>Study of<br>Bisoprolol<br>(Nerkardou)<br>(Between Low<br>Dose and High<br>Dose) 5 and 10 mg<br>ODF Treatment In<br>Egyptian Patients<br>with Essential<br>Hypertension | Interventional | IV | 1- Department<br>of General<br>Internal<br>Medicine<br>, Beni-Suef<br>University<br>Hospital<br>2- Department<br>of Cardiology<br>and vascular<br>medicine ,<br>Fayoum<br>University<br>Hospital | Approved<br>10-3-2024<br><br>Recruiting | Essential<br>Hypertension | Innovative<br><br>Nerkardou<br>(Bisoprolol)<br>Oral dispersible<br>film |

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