

Brighton and Sussex University Hospitals NHS Trust
Study Initiation Q2 2019 -2020

| Research Ethics Committee Reference Number | Integrated Research Application System Number | Name of Trial | First Participant Recruited? | Date of First Participant Recruited | Date Site Invited | Date Site Selected | HRA Approval Date | Date Site Confirmed By Sponsor | Date Site Confirmed | Non-Confirmation Status | Date Site Ready To Start | Reasons for Delay | Reasons for delay correspond to: |
|--|---|--|------------------------------|-------------------------------------|-------------------|--------------------|-------------------|--------------------------------|---------------------|------------------------------|--------------------------|--------------------|----------------------------------|
| 18/YH/0417 | 247000 | Phase 1 Multiple-Ascending-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of BILB078 Administered Intrathecally to Adults with C9ORF72-Associated Amyotrophic Lateral Sclerosis | No | | 29/11/2018 | 29/11/2018 | | | | Site declined to participate | | | Please Select... |
| 18/EM/0229 | 250101 | A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PARALLEL-GROUP, ACTIVE-CONTROL STUDY OF THE EFFICACY AND SAFETY OF SPARSENTAN FOR THE TREATMENT OF IMMUNOGLOBULIN A NEPHROPATHY | Yes | 16/04/2019 | 16/08/2018 | 08/10/2018 | 04/08/2018 | 12/11/2018 | 20/12/2018 | Please Select... | 16/01/2019 | D - Sponsor Delays | Sponsor |
| 18/WA/0154 | 233884 | WHITE 8 COPAL: A Randomised Controlled Trial of low dose single antibiotic loaded cement versus high dose dual antibiotic loaded cement in patients receiving a hip hemiarthroplasty after fracture | Yes | 26/04/2019 | 10/09/2018 | 21/11/2018 | 10/05/2018 | 28/02/2019 | 09/04/2019 | Please Select... | 09/04/2019 | | Please Select... |
| 17/LO/0871 | 215297 | Methylphenidate versus placebo for fatigue in advanced cancer (MePFAC) | Yes | 30/01/2019 | 28/08/2018 | 29/11/2018 | 23/05/2018 | 03/01/2019 | 09/01/2019 | Please Select... | 10/01/2019 | | Please Select... |
| 18/LO/2067 | 253346 | A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy | Yes | 19/04/2019 | 17/12/2018 | 17/12/2018 | 07/01/2019 | 11/03/2019 | 20/03/2019 | Please Select... | 09/04/2019 | | Please Select... |
| 18/LO/0555 | 237992 | Preventing Ovarian Cancer through early Excision of Tubes and late Ovarian Removal | Yes | 19/06/2019 | 28/01/2019 | 21/03/2019 | 19/04/2018 | 20/03/2019 | 20/05/2019 | Please Select... | 20/05/2019 | | Please Select... |
| 17/YH/0120 | 208838 | A pragmatic multi-centre randomised controlled non-inferiority, cost effectiveness trial comparing injections of collagenase into the cord to surgical correction in the treatment of moderate Dupuytren's Contracture in adult patients | Yes | 17/05/2019 | 21/12/2018 | 21/12/2018 | 25/05/2017 | 15/04/2019 | 17/04/2019 | Please Select... | 17/04/2019 | | Please Select... |
| 18/WA/0092 | 230113 | USTEKID – Phase II multi-centre, double-blind, randomised trial of Ustekinumab in adolescents with new-onset type 1 diabetes | Yes | 30/05/2019 | 02/01/2019 | 02/01/2019 | 21/09/2018 | 11/02/2019 | 30/04/2019 | Please Select... | 01/05/2019 | | Please Select... |

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| 18/EM/0193 | 243749 | A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PARALLEL, ACTIVE-CONTROL STUDY OF THE EFFECTS OF SPARSENTAN, A DUAL ENDOTHELIN RECEPTOR AND ANGIOTENSIN RECEPTOR BLOCKER, ON RENAL OUTCOMES IN PATIENTS WITH PRIMARY FOCAL SEGMENTAL GLOMERULOSCLEROSIS | No | | 15/01/2019 | 19/02/2019 | 18/09/2018 | 26/03/2019 | 24/04/2019 | Please Select... | 08/05/2019 | F - No patients seen | Neither |
| 18/LO/0324 | 220073 | The VIDEO Trial: A Feasibility RCT of Vitrectomy Plus Standard Care Intravitreal Ranibizumab Injections versus Standard Care Intravitreal Ranibizumab injections Alone In Patients With Centre Involving Diabetic Macular Edema | Yes | 01/05/2019 | 26/03/2019 | 26/03/2019 | 03/04/2019 | 26/03/2019 | 26/03/2019 | Please Select... | 26/03/2019 | D - Sponsor Delays | Sponsor |
| 18/LO/1453 | 246119 | BARBICAN: A randomised, open-label Phase II study to determine the contribution of ipatasertib to neoadjuvant chemotherapy plus atezolizumab in women with triple-negative breast cancer | No | | 27/03/2019 | 27/03/2019 | 15/11/2018 | | | Please Select... | | H - Contracting delays | Sponsor |
| 19/YH/0015 | 255446 | Beta Blockers or placebo for primary prophylaxis of oesophageal varices (BOPPP Trial). A blinded, multi-centre, clinical effectiveness and cost-effectiveness randomised controlled trial | Yes | 30/08/2019 | 27/03/2019 | 27/03/2019 | 24/04/2019 | 23/05/2019 | 17/06/2019 | Please Select... | 21/06/2019 | D - Sponsor Delays | Sponsor |
| 17/EE/0368 | 213669 | A randomised trial to assess whether the addition of a beta blocker infusion (landiolol) to standard treatment in patients with septic shock, requiring prolonged (>24 hours) support with high-dose vasopressor agents, improves organ failure (the STRESS-L trial) | No | | 10/01/2019 | 03/05/2019 | 10/11/2017 | | | Please Select... | | | Please Select... |
| 19/YH/0151 | 257273 | B7981015 - PF-06651600 IN ADULT AND ADOLESCENT ALOPECIA AREATA (AA) | No | | 09/11/2018 | 09/05/2019 | 24/07/2019 | 11/09/2019 | 16/09/2019 | Please Select... | | D - Sponsor Delays | Sponsor |
| 19/SW/0093 | 260867 | A Phase 2, Randomized, Double-blind, Placebo-controlled Evaluation of the Safety and Efficacy of BMS-986165 with Background Treatment in Subjects with Lupus Nephritis | No | | 25/04/2019 | 24/05/2019 | 17/06/2019 | 25/04/2019 | 04/09/2019 | Please Select... | | D - Sponsor Delays | Sponsor |
| 19/SC/0021 | 249552 | Optimal TIMING of Anticoagulation after acute ischaemic Stroke: a randomised controlled trial (OPTIMAS Trial) | No | | 13/06/2019 | 13/06/2019 | 04/04/2019 | | | Please Select... | | | Please Select... |
| 19/LO/0905 | 257865 | A Phase IV, Randomised, Open-Label Pilot Study to Evaluate Switching from Protease-Inhibitor based regimen to Bictegravir/Emtricitabine/Tenofovir Alafenamide Single Tablet Regimen in Integrase Inhibitor-naïve, virologically suppressed HIV-1 infected adults harbouring drug resistance mutations. | No | | 17/05/2019 | 28/06/2019 | 17/07/2019 | 05/09/2019 | 16/09/2019 | Please Select... | 16/09/2019 | | Please Select... |

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| 19/LO/0496 | 259483 | A Phase 3b Multicenter, Randomized, Double-Blind, Double-Dummy, Active Controlled Study Comparing the Safety and Efficacy of Upadacitinib to Dupilumab in Adult Subjects with Moderate to Severe Atopic Dermatitis | No | | 19/12/2018 | 15/01/2019 | 10/06/2019 | 24/07/2019 | 13/09/2019 | Please Select... | 13/09/2019 | | Please Select... |
| 18/LO/1187 | 240011 | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy | Yes | 08/07/2019 | 16/10/2018 | 21/01/2019 | 11/09/2018 | 21/03/2019 | 21/03/2019 | Please Select... | 11/04/2019 | G - No patients consented | Neither |
| 18/NW/0682 | 249138 | Clinical and Cost-effectiveness of Posterior Cervical Foraminotomy versus Anterior Cervical Discectomy in the Treatment of Cervical Brachialgia: A Multicentre, Phase III, Randomised Controlled Trial | No | | 19/02/2019 | 19/02/2019 | 19/11/2018 | | | Please Select... | | | Please Select... |
| 19/LO/0040 | 253233 | A PHASE 4, MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE IMPACT OF APREMILAST (CC-10004) ON QUALITY OF LIFE, EFFICACY, AND SAFETY IN SUBJECTS WITH MANIFESTATIONS OF PLAQUE PSORIASIS AND IMPAIRED QUALITY OF LIFE | No | | 04/03/2019 | 04/03/2019 | 15/08/2018 | 25/04/2019 | 15/05/2019 | Please Select... | 15/05/2019 | D - Sponsor Delays F - No patients seen | Sponsor |
| 19/EM/0034 | 255895 | A multicentre, randomised, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of padsevonil as adjunctive treatment of focal-onset seizures in adult subjects with drug-resistant epilepsy | No | | 15/05/2019 | 16/09/2019 | 16/06/2019 | 01/10/2019 | 01/10/2019 | Please Select... | | | Please Select... |
| 19/LO/0166 | 258220 | The VITALE Study Evaluating Safety and Effectiveness/Performance of the Microport CardioFlow VitaFlow II - Transcatheter Aortic Valve System. VitaFlowTM II Transcatheter Aortic Valve System Study | No | | 28/03/2019 | 15/07/2019 | 11/04/2019 | 25/09/2019 | | Please Select... | | | Please Select... |
| 19/LO/0738 | 258589 | A randomised, two-arm (1:1 ratio), double blind, placebo controlled phase III trial to assess the efficacy, safety, cost and cost-effectiveness of rituximab in treating de novo or relapsing NS in patients with MCD/FSGS (TURING) | No | | 17/07/2019 | 17/07/2019 | 14/06/2019 | | | Please Select... | | | Please Select... |

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| 18/WM/0394 | 248493 | Perioperative Childhood obesity (PEACHY): A prospective observational cohort study investigating the proportion of overweight and obese children presenting for a procedure under general anaesthesia in the UK and the incidence of preoperative adverse outcomes in this patient group | Yes | 10/09/2019 | 23/08/2019 | 23/08/2019 | 13/02/2019 | 10/09/2019 | 10/09/2019 | Please Select... | 10/09/2019 | | Please |
| 17/SC/0434 | 209815 | Biomarker-guided duration of antibiotic treatment for sepsis | No | | 25/04/2019 | 26/04/2019 | 23/10/2017 | | | Please Select... | | | Please Select... |
| 18/LO/1674 | 244500 | Randomised controlled trial of an app-based digital intervention to support breast cancer survivors prescribed hormone therapy (e-path study) | Yes | 09/10/2019 | 17/06/2019 | 31/07/2019 | 17/11/2018 | 30/09/2019 | 30/09/2019 | Please Select... | 30/09/2019 | | Please Select... |
| 18/SC/0624 | 244229 | Short or Long Antibiotic Regimes in Orthopaedics (SOLARIO): A Randomised Open Label Multi-Centre Clinical Trial | No | | 22/08/2019 | 22/08/2019 | 21/12/2018 | | | Please Select... | | | Please Select... |
| 17/YH/0311 | 229294 | A Modular, Multipart, Multiarm, Open-label, Phase I/IIa Study to Evaluate the Safety and Tolerability of CT7001 Alone and in Combination with Anti-cancer Treatments in Patients with Advanced Malignancies | No | | 19/06/2019 | 10/09/2019 | 30/10/2017 | | | Please Select... | | | Please Select... |
| 19/LO/1569 | 270111 | A phase 3b, open label treatment extension study of upadacitinib for the treatment of adult subjects with moderate to severe atopic dermatitis who successfully completed treatment in the M16-046 study | No | | 24/09/2019 | 24/09/2019 | | | | Please Select... | | | Please Select... |
| 19/LO/0802 | 264414 | Acceptability and tolerance study of high energy peptide supplement | No | | 29/05/2019 | 29/05/2019 | 21/05/2019 | | | Please Select... | | | Please Select... |
| 18/WA/0199 | 108978 | A randomised, placebo controlled trial of azithromycin for the prevention of chronic lung disease of prematurity in preterm infants | No | | 08/05/2019 | 18/07/2019 | 29/06/2018 | | | Please Select... | | | Please Select... |
| 19/SC/0507 | 265282 | RESPOND EDGE: Repositionable Lotus Edge™ Valve System – Post Market Evaluation of Real World Clinical Outcomes | No | | 30/09/2019 | 30/09/2019 | | | | Please Select... | | | Please Select... |
| 19/EM/0220 | 265213 | A Phase III, randomized, multicenter, open-label, non-inferiority study evaluating the efficacy, safety and tolerability of switching to dolutegravir/lamivudine fixed dose combination in HIV-1 infected adults who are virologically suppressed | No | | 22/08/2019 | 24/09/2019 | 11/09/2019 | | | Please Select... | | | Please Select... |
| 19/WM/0219 | 261627 | High Flow humidified oxygen as an early intervention in children with Acute Severe Asthma. A feasibility study (HiFlo ASA) | No | | 02/09/2019 | 02/09/2019 | 08/08/2019 | | | Please Select... | | | Please Select... |
| 19/LO/1217 | 264929 | Watchman FLX Left Atrial Appendage Closure Device Post Approval Study | No | | 05/09/2019 | 05/09/2019 | 04/09/2019 | | | Please Select... | | | Please Select... |