

Brighton and Sussex University Hospitals NHS Trust
Clinical Trials Initiation Performance Q1 2020 to 2021

| Research Ethics Committee Reference Number | Integrated Research Application System Number | Name of Trial | First Participant Recruited? | Date of First Participant Recruited | Duration between Date Site Selected and Date Site Confirmed | Duration between Date Site Confirmed and First Participant Recruited | Duration between Date Site Selected and 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 | Comments | Reasons for delay correspond to: |
|--|---|---|------------------------------|-------------------------------------|---|--|---|-------------------|--------------------|-------------------|--------------------------------|---------------------|-------------------------|--------------------------|----------------------|--|----------------------------------|
| 19/EM0034 | 255895 | A multicentre, randomised, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of padcevoneil as adjunctive treatment of focal-onset seizures in adult subjects with drug-resistant epilepsy | Yes | 03/12/2019 | 15 | 63 | 78 | 15/05/2019 | 16/09/2019 | 16/06/2019 | 01/10/2019 | 01/10/2019 | Please Select... | 23/10/2019 | J - Other | Contract signed electronically in error by host site too early | NHS Provider |
| 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 | Yes | 21/11/2019 | 128 | 1 | 129 | 28/03/2019 | 15/07/2019 | 11/04/2019 | 25/09/2019 | 20/11/2019 | Please Select... | 20/11/2019 | | Initiation target met | 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/PSGS (TURING) | Yes | 04/03/2020 | 223 | 8 | 231 | 17/07/2019 | 17/07/2019 | 14/06/2019 | 06/02/2020 | 25/02/2020 | Please Select... | 25/02/2020 | | Initiation target met | Please Select... |
| 18/W/M0394 | 248493 | PERiperAtive 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 | 18 | 0 | 18 | 23/08/2019 | 23/08/2019 | 13/02/2019 | 10/09/2019 | 10/09/2019 | Please Select... | 10/09/2019 | | Initiation target met | 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 | 14/10/2019 | 61 | 14 | 75 | 17/06/2019 | 31/07/2019 | 17/11/2018 | 30/09/2019 | 30/09/2019 | Please Select... | 30/09/2019 | | Initiation target met | Please Select... |
| 18/SC/0624 | 244229 | Short or Long Antibiotic Regimes in Orthopaedics (SOLARIO): A Randomised Open Label Multi-Centre Clinical Trial | Yes | 21/11/2019 | 24 | 13 | 37 | 22/08/2019 | 15/10/2019 | 21/12/2018 | 08/11/2019 | 08/11/2019 | Please Select... | 08/11/2019 | | Initiation target met | 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 | | 149 | | | 19/06/2019 | 10/09/2019 | 30/10/2017 | 12/11/2019 | 06/02/2020 | Please Select... | 06/02/2020 | F - No patients seen | Study temporarily closed due to COVID 19 and then no eligible pts seen | Neither |
| 18/WA/0199 | 108978 | A randomised, placebo controlled trial of azithromycin for the prevention of chronic lung disease of prematurity in preterm infants | No | | 230 | | | 08/05/2019 | 18/07/2019 | 29/06/2018 | 26/02/2020 | 04/03/2020 | Please Select... | 04/03/2020 | J - Other | Study recruitment was suspended due to COVID 19 | Neither |

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| 19/SC/0507 | 265282 | RESPOND EDGE: Repositionable Lotus Edge™ Valve System – Post Market Evaluation of Real World Clinical Outcomes | Yes | 06/01/2020 | 85 | 13 | 98 | 30/09/2019 | 30/09/2019 | 12/11/2019 | 05/12/2019 | 24/12/2019 | Please Select... | 24/12/2019 | | Initiation target met | 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/rilpivudine fixed dose combination in HIV-1 infected adults who are virologically suppressed | Yes | 02/12/2019 | 74 | 31 | 105 | 19/08/2019 | 19/08/2019 | 11/09/2019 | 11/10/2019 | 01/11/2019 | Please Select... | 01/11/2019 | | Initiation target met | Please Select... |
| 19/W/M/0219 | 261627 | High Flow humidified oxygen as an early intervention in children with Acute Severe Asthma. A feasibility study (HiFlo ASA) | Yes | 23/02/2020 | 168 | 6 | 174 | 02/09/2019 | 02/09/2019 | 08/08/2019 | 17/02/2020 | 17/02/2020 | Please Select... | 17/02/2020 | | Initiation target met | Please Select... |
| 19/LO/1217 | 264929 | Watchman FLX Left Atrial Appendage Closure Device Post Approval Study | Yes | 20/11/2019 | 71 | 6 | 77 | 28/05/2019 | 04/09/2019 | 04/09/2019 | 06/11/2019 | 14/11/2019 | Please Select... | 14/11/2019 | | Initiation target met - same day as sponsor green light! | Please Select... |
| 17/NW/0581 | 214739 | Does Interleukin-1 Receptor Antagonist Improve Outcome following aneurysmal Subarachnoid Haemorrhage (aSAH)? A Phase III trial | Yes | 17/10/2019 | 64 | 30 | 94 | 14/08/2018 | 15/07/2019 | 17/06/2019 | 06/11/2018 | 17/09/2019 | Please Select... | 17/09/2019 | H - Contracting delays | 10 days between CTA signature / CSC and Green Light. The Sponsor wouldn't release the drug unless we had issued CSC and then wouldn't issue Green Light until we had confirmed receipt of the drug and emergency un-blinding cards. Emergency unblinding cards had to be resent to site as they were opened in error by site pharmacy. | Both |
| 19/LO/0255 | 251219 | LITTLE JOURNEY: A multi-centre randomised controlled trial assessing the effectiveness of the Little Journey app at reducing peri-operative anxiety compared to standard care | No | | 133 | | | 04/09/2019 | 05/09/2019 | 08/05/2019 | 16/01/2020 | 16/01/2020 | Please Select... | 27/01/2020 | J - Other | Recruitment on hold - COVID 19 | Neither |
| 19/NW/0158 | 259931 | SCIENCE Surgery or Cast for Injuries of the Epicondyle in Children's Elbows. A multi-centre prospective randomised superiority trial of operative fixation versus non-operative treatment for medial epicondyle fractures of the humerus in children. | Yes | 09/12/2019 | 94 | 0 | 94 | 10/05/2019 | 06/09/2019 | 25/03/2019 | 25/11/2019 | 09/12/2019 | Please Select... | 09/12/2019 | | Initiation target met | Please Select... |
| 16/LO/1318 | 187932 | Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBeAg clearance. (NUC-B) | No | | 101 | | | 12/09/2018 | 18/10/2019 | 21/09/2016 | 16/01/2020 | 27/01/2020 | Please Select... | 17/02/2020 | J - Other | Recruitment suspended due to COVID 19 | Neither |
| 19/SW/0154 | 265849 | Visual and Optical outcomes after bilateral implantation of Tecnis Eyhance versus Rayner RayOne aspheric in patients undergoing routine cataract surgery | Yes | 13/11/2019 | 11 | 12 | 23 | 18/10/2019 | 21/10/2019 | 23/10/2019 | 01/11/2019 | 01/11/2019 | Please Select... | 01/11/2019 | | Initiation target met | Please Select... |
| 15/WA/0395 | 266296 | A randomised Phase III/II trial to study radiotherapy dose escalation in patients with oesophageal cancer treated with definitive chemo-radiation with an embedded Phase II trial for patients with a poor early response using positron emission tomography (PET) | Yes | 24/01/2020 | 188 | 8 | 196 | 11/01/2019 | 12/07/2019 | 31/10/2016 | 16/01/2020 | 16/01/2020 | Please Select... | 16/01/2020 | | Initiation target met | Please Select... |
| 20/NW/0035 | 272039 | A Phase 3, Randomized, Double-blind, Multicenter Study of Dostarlimab (TSR-042) plus Carboplatin-Faclitaxel versus Placebo plus Carboplatin-Faclitaxel in Patients with Recurrent or Primary Advanced Endometrial Cancer (RUBY) | No | | 285 | | | 28/11/2019 | 18/12/2019 | 20/03/2020 | 01/07/2020 | 28/09/2020 | Please Select... | 02/10/2020 | G - No patients consented | Participant approached within the initiation window but did not consent | Neither |

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| 19/WA/0325 | 266292 | A Randomised Controlled Trial of Early surgery in severe ASymptomatic Aortic Stenosis | No | | 235 | | | 10/01/2020 | 10/01/2020 | 20/04/2020 | 26/08/2020 | 01/09/2020 | Please Select... | 22/09/2020 | | No participants recruited, still within initiation target window | Please Select... |
| 20/NI/0004 | 260418 | Feasibility Study of the HighLife 28mm Trans-catheter Mitral Valve in Patients With Moderate-Severe or Severe Mitral Regurgitation and at High Surgical Risk | No | | 235 | | | 10/01/2020 | 10/01/2020 | 20/04/2020 | 26/08/2020 | 01/09/2020 | Please Select... | 22/09/2020 | | Still within initiation target window | Please Select... |
| 19/NE/0374 | 275170 | MKB591A-017 study – A Phase 3 Randomized, Active-Controlled, Open-Label Clinical Study to Evaluate a Switch to MKB591A (Istaravir/Doravirine) Once-Daily in Participants With HIV-1 Virologically Suppressed on Antiretroviral Therapy. | No | | 71 | | | 20/12/2020 | 15/01/2020 | 17/03/2020 | 13/03/2020 | 26/03/2020 | Please Select... | 30/03/2020 | J - Other | Recruitment put on hold - COVID 19 | Neither |
| 20/EE/0101 | 281712 | Randomised Evaluation of COVID-19 Therapy (RECOVERY) | Yes | 02/04/2020 | 4 | 7 | 11 | 17/03/2020 | 22/03/2020 | 17/03/2020 | 13/03/2020 | 26/03/2020 | Please Select... | 30/03/2020 | | Initiation target met | Please Select... |
| 20/SC/0154 | 281800 | A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalised Adults | Yes | 15/04/2020 | 13 | 9 | 22 | 24/03/2020 | 24/03/2020 | 26/03/2020 | 25/03/2020 | 06/04/2020 | Please Select... | 06/04/2020 | | Initiation target met | Please Select... |
| 20/YH/0063 | 266296 | A PHASE 3 OPEN-LABEL, MULTI-CENTER, LONG-TERM STUDY INVESTIGATING THE SAFETY AND EFFICACY OF PF-06651600 IN ADULT AND ADOLESCENT PARTICIPANTS WITH ALOPECIA AREATA | No | | | | | 04/06/2020 | 13/07/2019 | | | | Please Select... | | | Study in set up - not open to recruitment. The sponsor had to go back to REC. | Please Select... |
| 18/LO/0660 | 237150 | Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia | Yes | 12/06/2020 | 21 | 31 | 52 | 21/04/2020 | 21/04/2020 | 09/01/2020 | 07/05/2020 | 12/05/2020 | Please Select... | 26/05/2020 | | Initiation target met | Please Select... |
| 20/SC/0211 | 282109 | Chloroquine/ hydroxychloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting: a randomised, placebo-controlled prophylaxis study (COPCOV) | Yes | 21/05/2020 | 1 | 8 | 9 | 12/05/2020 | 12/05/2020 | 13/05/2020 | 28/04/2020 | 13/05/2020 | Please Select... | 21/05/2020 | | Initiation target met. | Please Select... |
| 20/EE/0135 | 282213 | Multiam Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs (TACTIC-R) | No | | 42 | | | 09/06/2020 | 09/06/2020 | 06/05/2020 | 21/07/2020 | 21/07/2020 | Please Select... | 02/08/2020 | F - No patients seen | Initiation target not met as COVID pt numbers were low at the time | Neither |