

**University Hospitals Sussex NHS Foundation Trust - Eastern
Clinical Trials Initiation Performance
Q2 2021 2022**

**Royal Sussex County Hospital
Royal Alexandra Children's Hospital
Princess Royal Hospital
Brighton General Hospital
Sussex Eye Hospital**

| 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 | Reasons for delay correspond to: |
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| 21/EE/0025 | 291420 | Acute treatment of angioedema attacks in Patients with hereditary angioedema due to C1-inhibitor Deficiency type I and II (RAPIDe-1) | Yes | 17/08/2021 | 193 | 113 | 306 | 15/10/2020 | 15/10/2020 | 12/04/2021 | 09/04/2021 | 26/04/2021 | Please Select... | 02/06/2021 | F - No patients seen | Neither |
| 20/LO/1114 | 1003435 | A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBO CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-9545 COMBINED WITH PALBOCICLIB COMPARED WITH LETROZOLE COMBINED WITH PALBOCICLIB IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER | Yes | 06/05/2021 | 140 | 58 | 198 | 20/10/2020 | 20/10/2020 | 18/12/2020 | 09/03/2021 | 09/03/2021 | Please Select... | 16/03/2021 | D - Sponsor Delays | Sponsor |
| 20/NW/0312 | 284188 | A Registry-based, Randomised, Double-blind, Placebo-Controlled Cardiovascular Outcomes Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Heart Failure or Cardiovascular Death in Patients without Diabetes with Acute Myocardial Infarction at Increased Risk for Subsequent Development of Heart Failure | Yes | 06/05/2021 | 133 | 62 | 195 | 23/10/2020 | 23/10/2020 | 23/07/2020 | 05/03/2021 | 05/03/2021 | Please Select... | 30/04/2021 | | Please Select... |
| 19/EM/0300 | 267054 | Effectiveness of an image analysing algorithm to diagnose non-melanoma skin cancers compared to gold standard histological determination | Yes | 13/12/2020 | 66 | -18 | 48 | 26/10/2020 | 26/10/2020 | 31/12/2020 | 04/12/2020 | 31/12/2020 | Please Select... | 31/12/2020 | | Please Select... |
| 20/YH/0317 | 288552 | Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older | Yes | 28/11/2020 | 15 | 15 | 30 | 28/10/2020 | 29/10/2020 | 10/11/2020 | 13/11/2020 | 13/11/2020 | Please Select... | 26/11/2020 | | Please Select... |
| 20/WM/0254 | 282486 | PARAvalvular leak closure with the Amplatzer Valvular Plug occluder for interventional transcatheter closure for PVL with surgical biological and Mechanical Heart Valve | Yes | 10/02/2021 | 71 | 1 | 72 | 30/11/2020 | 30/11/2020 | 06/11/2020 | 09/02/2021 | 09/02/2021 | Please Select... | 09/02/2021 | | Please Select... |
| 20/LO/1098 | 284919 | A UK interventional trial in premature infants With Apnoea of prematurity using a simple, non-invasive Vibratory device to study the Effectiveness in supporting breathing and general stability | No | | 96 | | | 09/01/2021 | 09/01/2021 | 11/11/2020 | 01/04/2021 | 15/04/2021 | Please Select... | 07/06/2021 | F - No patients seen | Neither |
| 20/NS/0110 | 278459 | SyncAV Post Market Trial | No | | 31 | | | 01/02/2021 | 01/02/2021 | 08/12/2020 | 04/03/2021 | 04/03/2021 | Please Select... | 23/03/2021 | F - No patients seen | Neither |
| 20/LO/1234 | 290834 | A randomized controlled trial to compare the safety and efficacy of sirolimus-eluting biodegradable polymer ultra thin stent (SUPRAFLEX™ Cruz) and everolimus-eluting biodegradable polymer stent (SYNERGY™) in treatment for threevessel coronary artery disease: Multivessel TALENT | Yes | 03/09/2021 | 94 | 106 | 200 | 04/11/2020 | 15/02/2021 | 12/02/2021 | 04/05/2021 | 20/05/2021 | Please Select... | 21/06/2021 | F - No patients seen | Neither |

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| 20/NW/0234 | 276873 | Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial (Simple Olecranon Fracture Fixation Trial - SOFFT) | No | | 161 | | | 16/03/2021 | 16/03/2021 | 16/06/2020 | 31/08/2021 | 24/08/2021 | Please Select... | | | Please Select... |
| 21/FT/0043 | 290151 | A Randomized Phase 3 Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants with Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer with Molecular Disease Based on Presence of Circulating Tumor DNA after Definitive Therapy (ZEST) | No | | 95 | | | 11/03/2021 | 17/03/2021 | 17/05/2021 | 28/06/2021 | 20/06/2021 | Please Select... | 16/07/2021 | F - No patients seen | Neither |
| 19/LO/1706 | 254799 | Feasibility Study of an Upper Limb functional training Programme to support self-management in Stroke Survivors | Yes | 12/05/2021 | 40 | 16 | 56 | 14/09/2020 | 17/03/2021 | 16/04/2020 | 20/04/2021 | 26/04/2021 | Please Select... | 26/04/2021 | | Please Select... |
| 21/NW/0035 | 1003512 | T-DM1 + Atazolizumab in high-risk HER2+ patients with residual disease after neoadjuvant taxane-based and HER2-targeted therapy | No | | 220 | | | 10/12/2020 | 10/12/2020 | 30/03/2021 | 04/05/2020 | 04/05/2020 | Please Select... | 24/06/2021 | F - No patients seen | Neither |
| 20/LO/0196 | 271343 | PreOperative Endocrine Therapy for Individualised Care with Abiraterone | Yes | 21/07/2021 | 185 | 22 | 207 | 21/12/2020 | 26/12/2020 | 08/07/2020 | 01/07/2021 | 29/06/2021 | Please Select... | 06/07/2021 | | Please Select... |
| 20/LO/1164 | 282017 | Clinical trial of atrial fibrillation patients comparing left atrial appendage occlusion therapy to non-vitamin K antagonist oral anticoagulants | No | | 36 | | | 27/01/2021 | 27/01/2021 | 26/01/2021 | 04/03/2021 | 04/03/2021 | Please Select... | 10/06/2021 | F - No patients seen | Neither |
| 20/LO/0065 | 271455 | A prospective, single arm clinical investigation evaluating safety and performance of the Colibri Transcatheter Aortic Heart Valve System for the treatment of asymptomatic severe aortic stenosis via transfemoral access in high surgical risk patients | No | | 23 | | | 03/02/2021 | 03/02/2021 | 26/01/2021 | 26/02/2021 | 26/02/2021 | Please Select... | 29/06/2021 | J - Other | Neither |
| 21/EE/0033 | 273987 | Comparative study of Advisor HD Grid versus Circular Mapping Catheters in assessment of pulmonary vein isolation following previous ablation for Atrial Fibrillation | Yes | 05/07/2021 | 116 | 28 | 144 | 03/02/2021 | 11/02/2021 | 15/03/2021 | 07/06/2021 | 07/06/2021 | Please Select... | 14/06/2021 | | Please Select... |
| 20/WA/0058 | 268723 | Procalcitonin and NEWS2 evaluation for Timely identification of Sepsis and Optimal use of antibiotics in the Emergency Department | No | | 62 | | | 17/03/2021 | 17/03/2021 | 22/07/2020 | 13/05/2021 | 18/05/2021 | Please Select... | | | Please Select... |

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| 21/NE/0067 | 272854 | A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF REGRETACOPLAN IN SUBJECTS WITH AMYOTROPHIC LATERAL SCLEROSIS (ALS) | No | | 57 | | | 28/04/2021 | 28/04/2021 | 28/04/2021 | 24/06/2021 | 24/06/2021 | Please Select... | 28/06/2021 | F - No patients seen | Neither |
| 19/WM/0266 | 266172 | Treatment of Hidradenitis Suppurativa Evaluation Study | Yes | 27/05/2021 | 1 | 40 | 41 | 16/04/2021 | 16/04/2021 | 03/10/2019 | 29/04/2021 | 17/04/2021 | Please Select... | 20/05/2021 | | Please Select... |
| 21/SC/0171 | 299180 | A randomised phase II UK multi-centre study to determine reactivity and immunogenicity of booster vaccination against ancestral and novel variants of SARS-CoV-2 | Yes | 10/06/2021 | 8 | 14 | 22 | 19/05/2021 | 19/05/2021 | 17/05/2021 | 27/05/2021 | 27/05/2021 | Please Select... | 28/05/2021 | | Please Select... |
| 19/LO/1741 | 263916 | Feasibility of frailty assessment and implementation of protocol-led geriatric interventions in women over the age of 70 with epithelial ovarian cancer in the oncology clinic (FAIR-O) | Yes | 23/08/2021 | 45 | 49 | 94 | 21/05/2021 | 21/05/2021 | 22/12/2019 | 30/06/2021 | 05/07/2021 | Please Select... | 06/07/2021 | D - Sponsor Delays | Sponsor |
| 20/WS/0178 | 290482 | A multicentre observer-blinded randomised controlled trial (RCT) with internal pilot and embedded process evaluation study | No | | | | | 29/06/2021 | 29/06/2021 | 24/05/2021 | | | Site declined to participate | | | Please Select... |
| 20/SC/0041 | 275334 | OPTimization of Left Main PCI with Intravascular Ultrasound. The OPTIMAL Randomized Controlled Trial | Yes | 01/10/2021 | 263 | 55 | 318 | 02/10/2020 | 17/11/2020 | 15/06/2020 | 29/07/2021 | 07/08/2021 | Please Select... | 24/08/2021 | F - No patients seen | Neither |
| 20/YH/0232 | 280105 | ATNEC - Axillary management in T1-3N1M0 breast cancer patients with FNA or core biopsy proven nodal metastases at presentation who convert to node negative after Neoadjuvant Chemotherapy | No | | | | | 04/03/2021 | 04/03/2021 | 22/10/2020 | | | Please Select... | | | Please Select... |
| 19/SC/0311 | 262176 | Primary Antibiotic prophylaxis using co-trimoxazole to prevent Spontaneous bacterial Peritonitis in Cirrhosis (ASEPTIC) | No | | 232 | | | 19/01/2021 | 19/01/2021 | 25/06/2019 | 08/09/2021 | 08/09/2021 | Please Select... | | | Please Select... |

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| 20/EE/0237 | 287122 | WATCHMAN FLX versus NOAC for Embolic Protection in the Management of Patients with Non-Valvular Atrial Fibrillation | No | | 201 | | | 26/11/2020 | 28/01/2021 | 28/01/2021 | 17/08/2021 | 17/08/2021 | Please Select... | 02/09/2021 | | Please Select... |
| 20/LO/0840 | 264482 | FUTURE-GB – Functional and Ultrasound guided Resection of Glioblastoma | No | | | | | 18/02/2021 | 03/05/2021 | 05/10/2020 | | | Please Select... | | | Please Select... |
| 20/SC/0403 | 288652 | PROphylaxis for pATIEnts at risk of COVID-19 infecTion | No | | 77 | | | 06/05/2021 | 06/05/2021 | 22/12/2020 | 22/07/2021 | 22/07/2021 | Please Select... | 27/07/2021 | F - No patients seen | Neither |
| 21/YH/0033 | 290847 | Breathing Retraining for Asthma Trial of Home Exercises for Teenagers: repurposing, refining and feasibility – Stage 3 | Yes | 07/09/2021 | 76 | 35 | 111 | 19/05/2021 | 19/05/2021 | 16/04/2021 | 15/02/2021 | 03/08/2021 | Please Select... | 03/08/2021 | | Please Select... |
| 20/EE/0252 | 276415 | Pharmacological management of seizures post traumatic brain injury (MAST) | No | | | | | 12/03/2021 | 28/05/2021 | 20/01/2021 | | | Please Select... | | | Please Select... |
| 21/NE/0092 | 294290 | Medtronic Cardiac Ablation (MCA) Registry, base CIP | No | | 19 | | | 02/07/2021 | 02/07/2021 | 11/08/2021 | 21/07/2021 | 21/07/2021 | Please Select... | | | Please Select... |
| 17/SC/0391 | 227067 | The High-Volume Hemofiltration vs High-flux Haemodialysis registry Trial | Yes | 21/09/2021 | 33 | 43 | 76 | 07/07/2021 | 07/07/2021 | 07/09/2017 | 06/08/2021 | 09/08/2021 | Please Select... | 09/08/2021 | F - No patients seen | Neither |
| 19/LO/1669 | 266322 | The RIO Trial: A randomised placebo controlled trial of ART plus dual long-acting HIV-specific broadly neutralising antibodies (bNABs) vs ART plus placebo in treated Primary HIV Infection on viral control off ART | No | | | | | 08/07/2021 | 08/07/2021 | 12/12/2019 | | | Please Select... | | | Please Select... |

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| 20/LO/0848 | 272164 | ALL Together1 - A Treatment study protocol of the ALL Together Consortium for children and young adults (1-15 years of age) with newly diagnosed acute lymphoblastic leukaemia | No | | | | | 13/05/2021 | 13/07/2021 | 25/01/2021 | | | Please Select... | | | Please Select... |
| 20/NW/0113 | 269405 | Dequalinium versus usual care antibiotics for the treatment of bacterial vaginosis (DEVA): a multicentre, randomised, open label, non-inferiority trial | No | | | | | 17/05/2021 | 13/08/2021 | 12/05/2020 | | | Please Select... | | | Please Select... |
| 20/YH/0230 | 285206 | A Feasibility Study of the Millipede Transcatheter Annuloplasty Ring System in Patients With Functional Mitral Regurgitation | No | | -38 | | | 09/02/2021 | 13/08/2021 | 31/08/2021 | 06/07/2021 | 06/07/2021 | Please Select... | | | Please Select... |
| 21/EM/0200 | 300599 | Testing the feasibility and acceptability of case-finding and subsequent comprehensive geriatric assessment intervention for older people with HIV | No | | | | | 06/09/2021 | 06/09/2021 | 15/09/2021 | | | Please Select... | | | Please Select... |
| 21/YH/0209 | 303827 | VROOM: Vaccine Response On/Off Methotrexate | No | | | | | 10/09/2021 | 10/09/2021 | 23/08/2021 | | | Please Select... | | | Please Select... |
| 21/LO/0412 | 288722 | Statins in Organ Donor Management - An evaluation of the benefits of a single dose of Simvastatin given to potential organ donors declared dead by neurological criteria on outcomes in organ recipients | No | | | | | 05/07/2021 | 17/09/2021 | 28/06/2021 | | | Please Select... | | | Please Select... |
| 19/LO/1064 | 260639 | The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter? | No | | | | | 10/08/2021 | 28/09/2021 | | | | Please Select... | | | Please Select... |
| 20/LO/0662 | 302286 | Prospective, Multicenter, Non-Randomized, Single-Arm, Open-Label Clinical Study to Demonstrate the Safety and Effectiveness of the ShortCut™ device (The ShortCut™ Study) | No | | | | | 17/08/2021 | 17/08/2021 | | | | Please Select... | | | Please Select... |