

**Brighton and Sussex University Hospitals NHS Trust
Study Initiation Q1 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/LO/0727	245123	Post-Market Clinical Follow-Up Study to Monitor Device Performance and Outcomes of the CENTERA Heart Valve System	Yes	14/02/2019	04/07/2018	04/07/2018	28/02/2018	04/07/2018	10/09/2018	Please Select...	05/10/2018	D - Sponsor Delays	Sponsor
18/SC/0243	240684	HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease	Yes	23/03/2019	24/07/2018	24/07/2018	01/10/2018	03/10/2018	01/10/2018	Please Select...	05/12/2018	D - Sponsor Delays F - No patients seen	Sponsor
17/LO/1711	234276	Synbiotic Extensively Hydrolysed Feed Study	Yes	08/01/2019	04/07/2018	25/07/2018	14/09/2018	25/07/2018	31/07/2018	Please Select...	14/09/2018	G - No patients consented	Neither
18/EE/0222	233921	A randomised controlled trial of very early versus delayed angiography +/-intervention on outcomes in patients with non ST-elevation myocardial infarction	Yes	12/12/2018	20/06/2018	27/07/2018	12/09/2018	26/09/2018	01/10/2018	Please Select...	03/10/2018	D - Sponsor Delays	Sponsor
18/LO/0997	216343	Brain Imaging to predict Toxicity in Elderly patients after Radiotherapy	Yes	05/09/2018	03/07/2018	01/08/2018	28/06/2018	01/08/2018	01/08/2018	Please Select...	08/08/2018	F - No patients seen	Neither
18/NW/0412	247770	To evaluate the acceptability (including gastro intestinal tolerance and compliance) of a low calorie peptide based paediatric tube-feed formula; for children greater than 1 year of age.	No		03/08/2018	03/08/2018	10/07/2018	03/08/2018	03/08/2018	Please Select...	03/08/2018	F - No patients seen	Neither

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18/LO/0612	235872	CLEAR SYNERGY (OASIS 9): A 2x2 factorial randomized controlled trial of Colchicine and spironolactone in patients with ST elevation myocardial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9	Yes	11/02/2019	28/05/2018	08/08/2018	16/07/2018	08/08/2018	17/09/2018	Please Select...	05/12/2018	D - Sponsor Delays	Sponsor
17/LO/1509	232288	A phase 3 randomised, double blind, clinical trial investigating the effectiveness of repurposed simvastatin compared to placebo, in secondary progressive multiple sclerosis, in slowing the progression of disability	Yes	23/10/2018	13/06/2018	18/09/2018	19/01/2018	12/07/2018	24/07/2018	Please Select...	18/09/2018	E - Staff availability issues	NHS Provider
18/LO/0995	244737	A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with Advanced	No		05/06/2018	21/09/2018	20/09/2018	17/08/2018	28/08/2018	Please Select...	14/11/2018	A - Permissions delayed/denied F - No patients seen	NHS Provider
18/LO/0864	245423	Safety & efficacy of Venetoclax + Fulvestrant in ER+ MBC patients	Yes	31/12/2018	03/07/2018	03/07/2018	19/09/2018	30/08/2018	04/09/2018	Please Select...	07/12/2018	A - Permissions delayed/denied	Neither
17/LO/2041	234256	Chronic Hypertension in pregnancy implementation study (CHAMPION)	Yes	01/08/2018	05/06/2018	09/07/2018	11/01/2018	09/07/2018	09/07/2018	Please Select...	09/07/2018		Please Select...

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18/WA/0161	238902	An open-label, multi-centre, randomised, switch study to evaluate the virological efficacy over 96 weeks of 2-drug therapy with DTG+RPV FDC in antiretroviral treatment-experienced HIV-1 infected subjects virologically suppressed with NNRTIs resistance mutation	Yes	18/01/2019	08/01/2018	06/08/2018	04/10/2018	13/11/2018	13/11/2018	Please Select...	13/11/2018	G - No patients consented	Neither
18/NW/0476	246649	Involve-CAT: A Feasibility Randomised Controlled Trial of a Cataract Decision Aid	Yes	09/10/2018	06/08/2018	06/08/2018	06/09/2018	17/09/2018	21/09/2018	Please Select...	26/09/2018		Please Select...
17/EM/0121	221773	A RANDOMIZED, OPEN, MULTINATIONAL, MULTICENTRE, 2-PART STUDY IN SPONTANEOUSLY BREATHING PRETERM NEONATES WITH MILD TO MODERATE RESPIRATORY DISTRESS SYNDROME TO INVESTIGATE THE SAFETY, TOLERABILITY AND EFFICACY OF INHALED NEBULISED PORACTANT ALFA (PORCINE SURFACTANT, CUROSURF®) IN COMPARISON WITH nCPAP ALONE	No		09/07/2018	23/08/2018	05/03/2019	24/09/2018	02/10/2018	Please Select...	24/04/2019	D - Sponsor Delays	Sponsor
18/EM/0229	250101	A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PARALLEL-GROUP, ACTIVE-CONTROL STUDY OF THE EFFICACY AND SAFETY OF SPARSENTAN FOR THE	No		16/08/2018	08/10/2018	04/08/2018	12/11/2018	20/12/2018	Please Select...	16/01/2019	D - Sponsor Delays F - No patients seen	Sponsor

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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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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				Please Select...			Please Select...
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		Please Select...			Please Select...
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				Please Select...			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				Please Select...			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			Site declined to participate			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	B - Suspended by sponsor	Sponsor