

# Brighton and Sussex University Hospitals NHS Trust

## Study Initiation Q3 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/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...
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...
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	22/10/2019	22/11/2019	Please Select...	25/11/2019	F - No patients seen H - Contracting delays	Neither
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	01/11/2019		Please Select...			Please Select...
19/YH/0151	257273	87981015 - PF-06651600 IN ADULT AND ADOLESCENT ALOPECIA AREATA (AA)	Yes	14/11/2019	09/11/2018	09/05/2019	24/07/2019	11/09/2019	16/09/2019	Please Select...	14/10/2019	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...	04/09/2019	D - Sponsor Delays	Sponsor

# Brighton and Sussex University Hospitals NHS Trust

## Study Initiation Q3 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:
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.	Yes	14/10/2019	17/05/2019	28/06/2019	17/07/2019	05/09/2019	16/09/2019	Please Select...	16/09/2019		Please Select...
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.	Yes	03/10/2019	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	Yes	29/10/2019	04/03/2019	04/03/2019	15/08/2018	25/04/2019	15/05/2019	Please Select...	15/05/2019	D - Sponsor Delays	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	Yes	03/12/2019	15/05/2019	16/09/2019	16/06/2019	01/10/2019	01/10/2019	Please Select...	23/10/2019	J - Other	NHS Provider
19/LO/0166	258220	The VITALE Study Evaluating Safety and Effectiveness/Performance of the Microport CardioFlow VitaFlow II - Transcatheter Aortic Valve System. VitaFlow™ II Transcatheter Aortic Valve System Study	Yes	21/11/2019	28/03/2019	15/07/2019	11/04/2019	25/09/2019	20/11/2019	Please Select...	20/11/2019		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...
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 Select...

## Brighton and Sussex University Hospitals NHS Trust

### Study Initiation Q3 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:
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	14/10/2019	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	Yes	21/11/2019	22/08/2019	15/10/2019	21/12/2018	08/11/2019	08/11/2019	Please Select...	08/11/2019		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/0802	264414	Acceptability and tolerance study of high energy peptide supplement	Yes	07/11/1979	29/05/2019	29/05/2019	21/05/2019	14/10/2019	31/10/2019	Please Select...	31/10/2019		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	21/05/2019		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	12/11/2019	05/12/2019	24/12/2019	Please Select...	24/12/2019		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	Yes	02/12/2019	19/08/2019	19/08/2019	11/09/2019	11/10/2019	01/11/2019	Please Select...	01/11/2019		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...

## Brighton and Sussex University Hospitals NHS Trust

### Study Initiation Q3 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:
19/LO/1217	264929	Watchman FLX Left Atrial Appendage Closure Device Post Approval Study	Yes	20/11/2019	28/05/2019	04/09/2019	04/09/2019	06/11/2019	14/11/2019	Please Select...	14/11/2019		Please Select...
19/EE/0185	260536	FIRST-line support for Assistance in Breathing in Children (FIRST-ABC): A master protocol of two randomised trials to evaluate the non-inferiority of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) for non-invasive respiratory support in paediatric critical care	Yes	04/12/2019	04/06/2019	04/06/2019	26/07/2019	31/10/2019	04/11/2019	Please Select...	04/11/2019		Please Select...
14/WA/1118	159836	A Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	No		13/06/2019	13/06/2019				Please Select...			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	14/08/2018	15/07/2019	17/06/2019	06/11/2018	17/09/2019	Please Select...	17/09/2019	H - Contracting delays	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		04/09/2019	05/09/2019	08/05/2019			Please Select...			Please Select...
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.	No		10/05/2019	06/09/2019	25/03/2019	25/11/2019	09/12/2019	Please Select...	09/12/2019		Please Select...
16/LO/1318	187932	Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBSAg clearance. (NUC-B)	No		12/09/2018	18/10/2019	21/09/2016			Please Select...			Please Select...
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	18/10/2019	21/10/2019	23/10/2019	01/11/2019	01/11/2019	Please Select...	01/11/2019		Please Select...