Brighton and Sussex University Hospitals NHS Trust
Clinical Trials Initiation Performance Q4 2019 2020

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:
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)	Yes	########	255	49	304	10/01/2019	03/05/2019	10/11/2017	01/11/2019	13/01/2020	Please Select...	13/01/2020		Initiation target met	Please Select...
19/YH/0151	257273	B7981015 - PF-06651600 IN ADULT AND ADOLESCENT ALOPECIA AREATA (AA)	Yes	########	130	59	189	09/11/2018	09/05/2019	24/07/2019	11/09/2019	16/09/2019	Please Select...	14/10/2019	D - Sponsor Delays	Multiple sponsor delays including IMP and training after we were requested to sign the contract. Sponsor not ready to green light site despite potential patients being available. 8 participants recruited	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		103			25/04/2019	24/05/2019	17/06/2019	25/04/2019	04/09/2019	Please Select...	04/09/2019	D - Sponsor Delays	Initiation target not met as sponsor wished for the contract to be signed before they had the PIS approved, in order to send out pharmacy supplies to site.	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...		J - Other	Site set up put on hold - COVID 19	Neither
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-naive, virologically suppressed HIV-1 infected adults harbouring drug resistance mutations.	Yes	########	80	28	108	17/05/2019	28/06/2019	17/07/2019	05/09/2019	16/09/2019	Please Select...	16/09/2019		Initiation target met and one of the first sites to open this study	Please Select...
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	########	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	########	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/FSGS (TURING)	Yes	########	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/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	########	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...
17/SC/0434	209815	Biomarker-guided duration of antibiotic treatment for sepsis	No					25/04/2019	26/04/2019	23/10/2017			Please Select...		J - Other	Site set up on hold - COVID 19	Neither
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	########	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	########	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

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19/LO/0802	264414	Acceptability and tolerance study of high energy peptide supplement	Yes	########	155	7	162	29/05/2019	29/05/2019	21/05/2019	14/10/2019	31/10/2019	Please Select...	31/10/2019		Initiation target met - first patient in across all sites	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		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
19/SC/0507	265282	RESPOND EDGE: Repositionable Lotus Edge™ Valve System – Post Market Evaluation of Real World Clinical Outcomes	Yes	########	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/lamivudine fixed dose combination in HIV-1 infected adults who are virologically suppressed	Yes	########	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/WM/0219	261627	High Flow humidified oxygen as an early intervention in children with Acute Severe Asthma. A feasibility study (HiFlo ASA)	Yes	########	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	########	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...
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	########	153	30	183	04/06/2019	04/06/2019	26/07/2019	31/10/2019	04/11/2019	Please Select...	04/11/2019		Initiation target met	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...			Study set up on hold - no PI allocated at site	Please Select...
17/NW/0581	214739	Does Interleukin-1 Receptor Antagonist Improve Outcome following aneurysmal Subarachnoid Haemorrhage (aSAH)? A Phase III trial	Yes	########	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 / C&C and Green Light. The Sponsor wouldn't release the drug unless we had issued C&C 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	########	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 HBsAg 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

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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	########	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 II/III 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	########	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-Paclitaxel versus Placebo plus Carboplatin-Paclitaxel 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
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-septal 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	MK8591A-017 study – A Phase 3 Randomized, Active Controlled, Open-Label Clinical Study to Evaluate a Switch to MK-8591A (Islatravir/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	########	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	########	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