

University Hospitals Sussex NHS Foundation Trust - Eastern
Clinical Trials Initiation Performance
Q3 2021 2022

Royal Sussex County Hospital
Royal Alexandra Children's Hospital
Princess Royal Hospital
Sussex Eye Hospital
Brighton General 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	Comments	Reasons for delay correspond to:
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	Yes	21/06/2021	96	67	163	09/01/2021	09/01/2021	11/11/2020	01/04/2021	15/04/2021	Please Select...	07/06/2021	F - No patients seen	Initiation target not met, no relevant 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	No eligible patients seen, participants falling screening	Neither
20/LO/1234	290834	A randomized controlled trial to compare the safety and efficacy of sirolimus-eluting biodegradable polymer ultra-thin stent (SUPRALIQ™) Cruz and everolimus-eluting biodegradable polymer stent (SYNERGY™) in treatment for three vessel 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	First participant recruited 03Sept2021. No relevant participants seen before that.	Neither
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...	25/10/2021	F - No patients seen	No relevant patients seen	Neither
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	Over 4 participants screened so far but none eligible for study intervention	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		Initiation target met	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	Yes	04/10/2021	36	216	252	22/01/2021	22/01/2021	26/01/2021	04/01/2021	04/01/2021	Please Select...	10/06/2021	F - No patients seen	No eligible 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 symptomatic 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	Initiation target not met, the relevant sponsor contacts couldn't be here for the procedure due to Covid 19 (first in man study)	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		Initiation target met	Please Select...

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20/WA/0058	268723	Procalcitonin and NEWS2 evaluation for Timely identification of Sepsis and Optimal use of antibiotics in the Emergency Department	Yes	08/10/2021	62	143	205	17/03/2021	17/03/2021	22/07/2020	13/05/2021	18/05/2021	Please Select...	16/09/2021		Initiation target met	Please Select...
21/NE/0067	272854	A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PEGCECTAPLAN IN SUBJECTS WITH ALMYOTROPIC 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	No eligible participants seen. Lots of pre-screens but all failed due to symptoms starting too long ago.	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		Initiation target met	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		Initiation target met	Please Select...
19/LD/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	Delays in receiving SOPs and green light to recruit from sponsor.	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			Site did not confirm capacity and capability - withdrew from the study set up for reasons relating to Covid repercussions	Please Select...
20/YH/0232	280105	ATNOC-Axillary management in T1-3N1M0 breast cancer patients with ER+ or core biopsy proven nodal metastases at presentation who convert to node negative after Neoadjuvant Chemotherapy	No					04/09/2021	04/09/2021	22/10/2020			Please Select...			Study still in set up at time of reporting - radiotherapy QA underway	Please Select...
19/SC/0311	262176	Primary Antibiotic prophylaxis using co-trimoxazole to prevent Spontaneous bacterial Peritonitis in Cirrhosis (ASEPTIC)	Yes	19/11/2021	233	71	304	19/01/2021	19/01/2021	25/06/2019	08/09/2021	09/09/2021	Please Select...	05/10/2021	F - No patients seen	FPR 19 Nov 2021 - prior to this there were screening fails	Neither
20/EE/0237	287122	WATCHMAN FLX versus NOAC for Embolic Protection in the Management of Patients with Non-Valvular Atrial Fibrillation	Yes	08/12/2021	201	113	314	26/11/2020	28/01/2021	28/01/2021	17/08/2021	17/08/2021	Please Select...	02/09/2021	F - No patients seen	No relevant patients seen	Neither

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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...			Study still in set up at time of reporting	Please Select...
20/SC/0403	288652	PROphylaxis for patients at risk of COVID-19 infection	Yes	02/09/2021	77	42	119	06/05/2021	06/05/2021	22/12/2020	22/07/2021	22/07/2021	Please Select...	24/08/2021		Initiation target met	Please Select...
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	19/09/2021	19/09/2021	16/04/2021	15/02/2021	03/08/2021	Please Select...	03/08/2021		Initiation target met	Please Select...
20/LE/0252	276415	Pharmacological management of seizures post traumatic brain injury (MAST)	No					12/03/2021	28/05/2021	20/01/2021			Please Select...			Study in set up at time of reporting	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...	29/11/2021	F - No patients seen	No relevant participants seen or recruited at the time of reporting	Neither
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	First participant recruited 21 Sept 2021 just outside the initiation recruitment window, no eligible participants seen prior to that.	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		125			08/07/2021	08/07/2021	12/12/2019	10/11/2021	10/11/2021	Please Select...	16/11/2021	F - No patients seen	First participant consented 30/12/2021 but not on study treatment (recruited according to DR definition) at time of reporting	Neither
20/LO/0848	272164	ALLTogether1 - A Treatment study protocol of the ALLtogether Consortium for children and young adults (1-45 years of age) with newly diagnosed acute lymphoblastic leukaemia	No					13/05/2021	13/07/2021	25/01/2021			Please Select...			Study in set up at time of reporting	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...			Study still in set up at time of reporting, an SV date is currently being agreed	Please Select...

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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...	29/11/2021	F - No patients seen	No relevant participants seen or recruited at the time of reporting	Neither
21/EM/0200	300599	Testing the feasibility and acceptability of case-finding and subsequent comprehensive geriatric assessment intervention for older people with HIV	Yes	22/11/2021	51	26	77	06/09/2021	06/09/2021	15/09/2021	19/07/2021	27/10/2021	Please Select...	08/11/2021		Initiation target met	Please Select...
21/YH/0209	303827	VRDOM: Vaccine Response On/Off Methotrexate	Yes	01/11/2021	27	25	52	10/09/2021	10/09/2021	23/08/2021	04/10/2021	07/10/2021	Please Select...			Initiation target met	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		48			05/07/2021	17/09/2021	28/06/2021	28/10/2021	04/11/2021	Please Select...	09/11/2021	F - No patients seen	No relevant participants seen or recruited at the time of reporting	Neither
19/LD/1064	260639	The TIGHT-K STUDY - Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?	No		34			10/08/2021	28/09/2021	06/11/2019	28/10/2021	01/11/2021	Please Select...	17/11/2021	F - No patients seen	No relevant participants seen or recruited at time of reporting	Neither
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...			Study still in set up at time of reporting, awaiting final HRA pack.	Please Select...
21/YT/0109	1004071	A Phase 3 Open-label Rollover Clinical Study of Doravirine/Islatravir (DOR/ISL) Once-daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL in a Phase 2 or Phase 3 DOR/ISL Clinical Study	No		70			23/08/2021	23/08/2021	04/10/2021	28/10/2021	01/11/2021	Please Select...	24/11/2021	J - Other	Rollover study only	Neither

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21/NW/0228	1003836	Evaluating the clinical and cost-effectiveness of Sodium Bicarbonate administration for critically ill patients with Acute Kidney Injury and metabolic acidosis	No					15/10/2021	15/10/2021				Please Select...			Study still in set up at time of reporting	Please Select...
21/SC/0385	302606	A Phase II, Double-blind, Placebo-controlled, Randomized, Dose-ranging, Parallel Group Study to Evaluate the Safety and Efficacy of PHS-02121 Administered Orally for Prophylaxis Against Angioedema Attacks in Patients with Hereditary Angioedema due to C1-Inhibitor Deficiency (Type I or Type II)	No					15/07/2021	01/11/2021				Please Select...			Study still in set up at time of reporting	Please Select...
21/LO/0851	250846	A Double-Blind, Multicentre, Placebo Controlled, Parallel Group Design to Assess the Efficacy, Safety and Dose Response Characterisation of a Controlled Release Formulation of Dihydroal for the Treatment of Mild-Moderate Alopecia Areata (AA)	No					27/09/2021	12/11/2021	10/12/2021			Please Select...			Study still in set up at time of reporting.	Please Select...
19/SC/0634	252084	Treating severe paediatric asthma: a randomised controlled trial of mepolizumab and omalizumab (TREAT trial)	No					16/11/2021	16/11/2021				Please Select...			Study still in set up at time of reporting.	Please Select...
21/NS/0121	293866	Prospective, Single-arm Study to Assess the Safety and Performance of the Omega™ Left Atrial Appendage (LAA) Occluder in Patients with Non-Valvular Atrial Fibrillation and High Bleeding Risk	No					19/11/2021	19/11/2021	11/11/2021			Please Select...			Study still in set up at time of reporting	Please Select...
21/N/0116	299168	HighLife Trans-Septal Mitral Valve Replacement (TSMVR) Feasibility Study of the Open Cell CLARITY valve in patients with moderate-severe or severe mitral regurgitation, high surgical risk and with a high risk for Left Ventricular Outflow Tract Obstruction (LVOTO)	No		35			28/06/2021	28/06/2021	21/12/2021	22/07/2021	02/08/2021	Please Select...			Study still in set up at time of reporting: await SV and regulatory approvals	Please Select...