

University Hospitals Sussex NHS Foundation Trust - Eastern Sites
Clinical Trials Initiation Performance
Q1 2021 to 2022

Royal Sussex County Hospital
Royal Alexandra Children's Hospital
Princess Royal Hospital
Brighon 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	Comments	Reasons for delay correspond to:
20/WA/0121	276396	British Heart Foundation Randomised Clinical Trial of Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI)	Yes	11/11/2020	110	15	125	09/07/2020	09/07/2020	11/09/2020	16/10/2020	27/10/2020	Please Select...	02/11/2020		Initiation target met	Please Select...
20/LO/0158	268803	Randomized Comparison of Abluminus DES+ Sirolimus-Eluting Stents versus Everolimus-Eluting Stents in Coronary Artery Disease Patients with Diabetes Mellitus (ABILITY Diabetes Global)	Yes	26/11/2020	88	45	133	16/07/2020	16/07/2020	16/07/2020	02/10/2020	12/10/2020	Please Select...	26/11/2020		Initiation target met	Please Select...
20/EM/0209	286545	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)	No		229			20/08/2020	20/08/2020	13/10/2020	06/04/2021	06/04/2021	Please Select...	07/05/2021	F - No patients seen	No eligible patients seen, aiming for one recruit across the duration of the study so , rare indication	Neither
20/EE/0178	257470	Simultaneous Endo-Epicardial Mapping of Recurrent Atrial Fibrillation	Yes	21/01/2021	57	93	150	24/08/2020	24/08/2020	21/08/2020	20/10/2020	20/10/2020	Please Select...	24/11/2020	F - No patients seen	First patient recruited 21Jan2021 - no relevant patients seen prior to that.	Neither
20/NE/0201	286160	A Phase 3 Global, Multicenter, Double-Blind Randomized Study of Carboplatin-Paclitaxel With INCMGA00012 or Placebo in Participants With Inoperable Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Anal Canal Not Previously Treated With Systemic Chemotherapy (POD1UM-303/ InterAACT 2)	No		144			01/06/2020	03/09/2020	08/10/2020	21/01/2021	25/01/2021	Please Select...	01/03/2021	F - No patients seen	No eligible patients seen	Neither
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)	No		193			15/10/2020	15/10/2020	12/04/2021	09/04/2021	26/04/2021	Please Select...	02/06/2021	D - Sponsor Delays	Sponsor delays in providing supplies such as ePRO, training and login details for study systems	Sponsor
20/LO/1114	1003435	A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBOCONTROLLED, 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	No		140			20/10/2020	20/10/2020	18/12/2020	09/03/2021	09/03/2021	Please Select...	16/03/2021	D - Sponsor Delays	Delays in greenlight from sponsor, no patients seen	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		Initiation target met, first patient recruited 06 May 2021	Please Select...

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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		Initiation target met	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		Initiation target met	Please Select...
20/WM/0254	282486	PARAvalvular leak closure with the Amplatzer Valvular Plug occluder for Interventional transcatheter closure for PVL with surgical bioGical 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		Initiation target met, first patient recruited 10Feb2021	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	No eligible 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, first participant failed screening	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.	No		94			04/11/2020	15/02/2021	12/02/2021	04/05/2021	20/05/2021	Please Select...			Study still in set up at time of reporting	Please Select...
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					16/03/2021	16/03/2021	16/06/2020			Please Select...			Study still in set up at the time of reporting	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...			Study still in set up at the time of data reporting	Please Select...

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20/LO/1164	282107	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	No eligible patients seen	Neither
20/LO/0065	271455	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			Please Select...
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...
19/LO/706	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	17/04/2020	20/04/2021	26/04/2021	Please Select...	26/04/2021		Initiation target met	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...			Study in set up at time of reporting	Please Select...
21/NE/0067	272854	A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PEGCETACOPLAN 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...			Study still in set up at time of reporting	Please Select...
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/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)	No					21/05/2021	21/05/2021	22/12/2019	30/06/2021		Please Select...			Study still in set up at time of reporting	Please Select...
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			Please Select...			Study still in set up at time of reporting	Please Select...