

**Brighton and Sussex University Hospitals NHS Trust
Clinical Trials Initiation Performance Q4 2020 to 2021**

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:
18/LO/0660	237150	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia	Yes	12/06/2020	21	31	52	21/04/2020	21/04/2020	09/01/2020	07/05/2020	12/05/2020	Please Select...	26/05/2020		Initiation target met	Please Select...
20/SC/0211	282109	Chloroquine/ hydroxychloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting: a randomised, placebo-controlled prophylaxis study (COPCOV)	Yes	21/05/2020	1	8	9	12/05/2020	12/05/2020	13/05/2020	28/04/2020	13/05/2020	Please Select...	21/05/2020		Initiation target met, first participant recruited on day of opening study.	Please Select...
20/EE/0135	282213	Multiam Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs (TACTIC-R)	No		42			09/06/2020	09/06/2020	06/05/2020	21/07/2020	21/07/2020	Please Select...	02/08/2020	F - No patients seen	Initiation target not met as COVID pt numbers were low at the time (pre second wave)	Neither
20/W/M/0054	264593	CRAFT - Children's Radius - Acute Fracture Fixation Trial: A Multi-Centre Prospective Randomised Surgical Reduction versus Non Surgical Casting for Displaced Distal Radius Fractures in Children.	Yes	23/12/2020	175	75	250	17/04/2020	17/04/2020	16/04/2020	02/10/2020	09/10/2020	Please Select...	12/10/2020	F - No patients seen	First patient recruited 23/12/2020 within 30 days of RSCH site being ready to start - prior to this there were two screen failures.	Neither
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 Abilumab 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					20/08/2020	20/08/2020	13/10/2020			Please Select...			Study set up was delayed due to Covid 19, still in set up and contracts pending at the time of reporting. Nearly ready to issue local C&C.	Please Select...
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 21 Jan 2021 - no relevant patients seen prior to that.	Neither
20/NE/0201	286160	A Phase 3 Global, Multicenter, Double-Blind Randomized Study of Carboplatin-Faclitaxel With INCMGA0012 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/InterACT 2)	No					01/06/2020	03/09/2020	08/10/2020			Please Select...			Study still in set up at time of reporting. Aiming to open in the very near future.	Please Select...

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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					15/10/2020	15/10/2020				Please Select...			HRA approval pending and therefore study still in set up at time of reporting.	Please Select...
20/LO/1114	1003435	A PHASE III RANDOMIZED, DOUBLE-BLIND, PLACEBOCONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF GDC-0995 COMBINED WITH PALBOCICLIB COMBINED 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...	04/03/2021		C&C issued 04March2021	Please Select...
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	No		133			23/10/2020	23/10/2020	23/07/2020	05/03/2021	05/03/2021	Please Select...			Study still in set up at the time of reporting, expect to open to recruitment in the near future.	Please Select...
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.COV.2.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 biological 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					09/01/2021	09/01/2021	11/11/2020			Please Select...			Study still in set up at time of data reporting, the sponsor is processing some amendments at site.	Please Select...
20/NS/0110	278459	SyncAV Post Market Trial	No					01/02/2021	01/02/2021	08/12/2020			Please Select...			Study still in set up at the time of data reporting.	Please Select...
20/LO/1234	290834	A randomized controlled trial to compare the safety and efficacy of sirolimus-eluting biodegradable polymer ultra-thin stent (SUPRAREX™ Cruz) and everolimus-eluting biodegradable polymer stent (SYNERGY™) in treatment for threevessel coronary artery disease: Multivessel TALENT.	No					04/11/2020	15/02/2021	12/02/2021			Please Select...			Study still in set up at the time of data 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 data 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					11/03/2021	17/03/2021				Please Select...			Study still in set up at the time of data reporting	Please Select...
19/LO/1414	254799	Feasibility Study of an Upper Limb functional training Programme to support self-management in Stroke Survivors	No					14/09/2020	17/03/2021	16/04/2020			Please Select...			Study still in set up at the time of data reporting	Please Select...