

Brighton and Sussex University Hospitals NHS Trust
Clinical Trials Initiation Performance Q3 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:
19/WA/0325	266292	A Randomised Controlled Trial of Early surgery in severe ASymptomatic Aortic Stenosis	Yes	09/02/2021	235	161	396	10/01/2020	10/01/2020	20/04/2020	26/08/2020	01/09/2020	Please Select...	22/09/2020	F - No patients seen	No relevant patients seen	Neither
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	F - No patients seen	No participants recruited to date despite screening. No relevant patients seen.	Neither
19/NE/0374	275170	MK8591A-017 study – A Phase 3 Randomized, Active-Controlled Open-Label Clinical Study to Evaluate a Switch to MK-8591A (Istravir/Doravirine) Once-Daily in Participants With HIV-1 Virologically Suppressed on Antiretroviral Therapy.	Yes	28/02/2020	36	8	44	20/12/2019	15/01/2020	20/01/2020	20/02/2020	20/02/2020	Please Select...	26/02/2020		Initiation target met	Please Select...
20/EE/0101	281712	Randomised Evaluation of COVID-19 Therapy (RECOVERY)	Yes	02/04/2020	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	15/04/2020	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...
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	Multicarm 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/WM/0004	276801	Clinical Investigation of Patient Outcomes after IOL Implantation with Different IOL Delivery Systems	Yes	12/11/2020	300	9	309	03/12/2019	08/01/2020	24/02/2020	03/11/2020	03/11/2020	Please Select...	03/11/2020		Initiation target met	Please Select...
19/SC/0497	260938	A Phase III, Randomized, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepolixacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhoea Caused by Neisseria gonorrhoeae	No					02/12/2019	16/01/2020				Please Select...		J - Other	03/07/2020 Site temporarily withdrew due to COVID 19 pandemic in light of endoscopy service changes related to that. Study is in set up again.	Neither

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19/EE/0380	274031	A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Study to Investigate the Use of Benralizumab for Eosinophilic Esophagitis (MESSINA)	No					03/01/2020	27/01/2020				Please Select...			Study set up was put on hold due to the COVID 19 pandemic and study is in set up again.	Please Select...
19/LO/1953	271361	Efficacy of BIC/F/TAF versus standard of care in the treatment of new HIV infection diagnoses in the context of 'test and treat'	No					03/02/2020	03/02/2020	26/03/2020			Please Select...			Study still in set up - nearly ready to issue C&C at time of reporting	Please Select...
20/WM/0054	264593	CRAFFT – 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.Jan2021 - 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					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...
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...

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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...	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...				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/W/M/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