

Number	Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) Number	Name of Trial	Date site was invited	Date site was selected	HRA Approval Date	Date site was confirmed by sponsor	Date site was confirmed	Date site was ready to start	Date of the recruitment of first patient	Reasons for delay correspond to:	Comments
1	19/NW/0716	273613	A Phase 3b Open-label Study Evaluating the Safety of Elexacaftor/Tezacaftor/Ivacaftor Combination Therapy in Cystic Fibrosis Subjects	25/03/2020	08/04/2020	17/01/2020	08/04/2020	14/04/2020	14/04/2020	18/06/2020	Sponsor	Initials delays with recruitment were caused by sponsor suspending study due to COVID-19
2	18/LO/0660	237150	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia	06/04/2020	07/04/2020	23/07/2018	08/04/2020	14/04/2020	14/04/2020	20/04/2020	Please select	
3	20/HRA/1696	282338	Ventilation Strategies in COVID-19; CPAP, High-flow, and standard care	23/04/2020	23/04/2020	03/04/2020	23/04/2020	23/04/2020	23/04/2020	29/09/2020	Neither	No patient presented due to the strict criteria eligibility
4	20/SC/0179	281904	A phase 2/3 study to determine the efficacy, safety and immunogenicity of the candidate Coronavirus Disease (COVID-19) vaccine ChAdOx1 nCoV-19	07/05/2020	20/05/2020	04/05/2020	21/05/2020	21/05/2020	21/05/2020	26/05/2020	Please select	
5	20/LO/0279	277975	ReCerf® total hip resurfacing	11/06/2020	11/06/2020	22/04/2020	18/06/2020	22/06/2020	22/06/2020	30/06/2020	Please select	
6	20/SC/0201	282769	ACCORD 2: A Multicentre, Seamless, Phase 2 Adaptive Randomisation Platform Study to Assess the Efficacy and Safety of Multiple Candidate Agents for the Treatment of COVID 19 in Hospitalised Patients	28/05/2020	03/06/2020	28/04/2020	05/06/2020	08/06/2020	08/06/2020	18/06/2020	Please select	
7	20/HRA/2191	283184	Recombinant InterLeukin-7 (CYT107) to Improve clinical outcomes in lymphopenic patients with COVID-19 infection "ILIAD 7 trial"	10/06/2020	16/06/2020	06/05/2020	18/06/2020	23/06/2020	23/06/2020	24/11/2020	Neither	No patients presented initially due to the strict criteria eligibility
8	18/LO/0508	241903	An Open-Label, Multicentre, Long-Term Follow-Up Study to Investigate the Safety and Durability of Response Following Dosing of a Novel Adeno-Associated Viral Vector (FLT180a) in Patients With Haemophilia B	19/02/2020	08/07/2020	15/05/2018	09/07/2020	09/07/2020	09/07/2020	13/07/2020	Please select	
9	20/EE/0135	282213	Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs (TACTIC-R)	22/06/2020	16/07/2020	06/05/2020	17/07/2020	17/07/2020	20/07/2020	01/10/2020	Neither	No patients presented due to the strict criteria eligibility initially
10	20/YH/0090	278137	AN OPEN-LABEL, MULTICENTER, ROLLOVER STUDY TO EVALUATE THE SAFETY AND TOLERABILITY OF LONG-TERM ADMINISTRATION OF GANTERUMABIN PARTICIPANTS WITH ALZHEIMER'S DISEASE	27/05/2020	12/08/2020	20/04/2020	14/08/2020	14/08/2020	17/08/2020	04/11/2020	Neither	This study deals with a rare disease no patient presented to the team until Q3
11	19/LO/1837	271981	An Open-label, Multicenter Trial of the Safety, Tolerability, and Pharmacokinetic/Pharmacodynamic Profile of M1774 in Participants with Metastatic or Locally Advanced Unresectable Solid Tumors	30/03/2020	16/06/2020	14/01/2020	23/07/2020	12/08/2020	12/08/2020	06/10/2020	Neither	Initial delays with set up were due to COVID-19. No eligible patient initially were seen once the study was approved. This study deals with a rare disease
12	19/LO/1753	269460	A phase 2, randomized, double-blind, placebo controlled study to evaluate the safety, efficacy, pharmacodynamics, and pharmacokinetics of SAR339375 for subcutaneous injection administered every week in patients with Alport Syndrome	29/06/2020	21/07/2020	13/02/2020	20/07/2020	03/08/2020	03/08/2020	20/08/2020	Please select	

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13	17/WA/0155	223941	Primary care Management of lower Urinary tract Symptoms in men: Development and validation of a diagnostic and decision-making aid.	21/01/2020	09/09/2020	23/08/2017	29/09/2020	29/09/2020	29/09/2020	10/12/2020	Neither	The team screened patients at the weekly clinic and initially no eligible patients were found until December
14	19/LO/1195	261755	A randomized, double-blind, placebo-controlled adjuvant trial in newly diagnosed primary glioblastoma subjects to assess the efficacy and safety of 2-hydroxyoleic acid (2-OHOA) in combination with radiotherapy and temozolomide standard of care treatment	17/08/2020	15/09/2020	05/12/2019	21/09/2020	28/09/2020	28/09/2020	04/11/2020	Please select	
15	20/NE/0058	275056	A Multicenter, Open-label, Randomized Phase 2 Study to Compare the Efficacy and Safety of Lenvatinib in Combination with Ifosfamide and Etoposide versus Ifosfamide and Etoposide in Children, Adolescents and Young Adults with Relapsed or Refractory Osteosarcoma (OLIE)	23/07/2020	21/08/2020	30/04/2020	03/09/2020	14/09/2020	15/09/2020	15/12/2020	Neither	Due to the nature of the disease criteria. This study focuses on relapsed osteosarcoma and we did not have any relapsed patients until December
16	19/NE/0357	271261	A Phase 3, Multinational, Multicenter, Double-Blind, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of Aramchol in Subjects with Nonalcoholic Steatohepatitis (NASH) The ARMOR Study	29/11/2019	30/07/2020	06/01/2020	31/08/2020	01/09/2020	01/09/2020		Sponsor	Because of the pandemic, the sponsor put on hold recruitment whilst they revised their protocol.
17	19/NI/0126	254829	SMALL: A Phase III, randomised, multi-centre trial addressing overtreatment of small screen-detected breast cancer by comparing standard surgery versus minimally invasive vacuum-assisted excision	09/03/2020	14/09/2020	15/10/2019	17/09/2020	18/09/2020	25/09/2020	25/03/2021	Neither	Delays with recruitment were due to the pandemic
18	19/LO/1949	274671	AN OPEN-LABEL, MULTI-CENTRE, PHASE Ib/II STUDY EVALUATING THE SAFETY AND EFFICACY OF AUTO1, A CAR T CELL TREATMENT TARGETING CD19, IN ADULT PATIENTS WITH RELAPSED OR REFRACTORY B CELL ACUTE LYMPHOBLASTIC LEUKAEMIA	06/08/2020	06/08/2020	17/02/2020	10/09/2020	14/09/2020	15/09/2020	28/09/2020	Please select	
19	19/SC/0107	237804	A phase II trial assessing nivolumab in strong class II expressing microsatellite stable colorectal cancer	04/08/2020	04/08/2020	05/07/2019	18/09/2020	21/09/2020	21/09/2020	15/10/2020	Sponsor	Initial delays were due to contracting delays within the sponsor company
20	20/YH/0174	283089	A randomised, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV in patients with severe pulmonary COVID-19 related disease.	11/06/2020	29/07/2020	20/05/2020	01/09/2020	02/09/2020	02/09/2020	03/11/2020	Neither	No patients seen initially due to COVID-19 and the strict eligibility criteria

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21	19/LO/0062	255909	A Study evaluating the Efficacy and Safety of Ralipag To Improve Treatment OUTCOMES in PAH Patients	11/12/2019	24/09/2020	03/04/2019	13/10/2020	15/10/2020	15/10/2020		Neither	No patient were identified initially however, two patients are identified and awaiting to achieve stable background treatment to make them eligible for the protocol. This strategy has been communicated and agreed with Sponsor
22	19/LO/0063	255904	A Study Evaluating the Long-Term Efficacy and Safety of Ralipag in Subjects with PAH via an Open-Label EXTENSION	11/02/2019	24/09/2020	04/04/2019	13/10/2020	15/10/2020	15/10/2020		Neither	This study is a sub study and as there are no patients in the main study ADVANCE 301 and we are unable to recruit however, two patients identified are awaiting to achieve stable background treatment to make them eligible for the protocol. This strategy has been communicated and agreed with Sponsor
23	19/NW/0046	227794	A parallel arm, biomarker driven, phase II feasibility trial to determine the role of circulating tumour DNA in guiding a switch between targeted therapy and immune therapy in patients with advanced cutaneous melanoma	11/05/2020	25/09/2020	26/03/2019	29/09/2020	01/10/2020	13/10/2020		Neither	This study deals with rare patients and none have been identified that meet the strict eligibility based on their liver function
24	19/YH/0222	252494	Positional Therapy for Obstructive Sleep Apnoea: a Randomised Controlled Trial to assess the effect on Health and Wellbeing in Older and Younger People.	05/03/2020	12/08/2020	24/07/2019	13/10/2020	13/10/2020	14/10/2020	25/11/2020	Neither	Initial set up was suspended due to COVID-19
25	18/YH/0358	242342	A randomised controlled trial to establish the clinical and cost effectiveness of expectant management versus pre-operative imaging with Magnetic Resonance Cholangiopancreatography (MRCP) in patients with symptomatic gallstones undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones	02/03/2020	02/10/2020	12/12/2018	02/10/2020	02/10/2020	06/10/2020	26/11/2020	Please select	
26	19/NE/0361	272352	A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study to Evaluate the Efficacy and Safety of VIB4920 in subjects with Sjogren's Syndrome (SS)	21/07/2020	21/07/2020	15/01/2020	20/08/2020	15/10/2020	15/10/2020		Sponsor	Initial set up was suspended due to COVID-19. A contract amendment is still going through to change elements of the protocol causing delays to patient recruitment
27	20/EE/0031	275993	Randomized, placebo controlled, double-blind, parallel group, dose-finding Phase 2 study to evaluate efficacy and safety of BAY 2433334 in patients following an acute non-cardioembolic ischemic stroke	21/01/2020	03/08/2020	03/04/2020	16/10/2020	20/10/2020	20/10/2020	31/12/2020	Sponsor	Initial delays were caused by contracting delays with the sponsor then greenlight was not given until November. Study opened to recruitment early December 2020
28	19/SW/0191	270987	Ross for Valve replacement in Adults(REVIVAL) Registry	11/05/2020	11/05/2020	30/01/2020	17/07/2020	20/10/2020	20/10/2020	31/07/2021	Neither	Initial set up was suspended due to COVID-19. No patients were seen due to the elective lists being cancelled initially due to the pandemic
29	19/LO/1664	261665	Patient Reported Outcomes in patients with Persistent Rheumatoid Arthritis (PROsPer-RA)	18/03/2020	21/08/2020	26/11/2019	28/10/2020	29/10/2020	30/10/2020		Neither	Initial set up was suspended due to COVID-19 and site opening was hugely delayed. No patients have been seen since restarting study
30	20/NE/0052	277285	Elite Study	17/09/2020	21/10/2020	15/04/2020	27/10/2020	27/10/2020	29/10/2020	08/12/2020	Please select	
31	19/NE/0263	261557	Open label, long-term safety, tolerability, and efficacy study of GIVINOSTAT in all DM1 patients who have been previously treated in one of the GIVINOSTAT studies.	27/02/2020	14/09/2020	04/03/2020	20/10/2020	21/10/2020	21/10/2020	11/11/2020	Please select	

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32	20/NE/0189	280542	Feasibility study for identification of patients at potential risk of silent aspiration in an acute stroke setting: a comparison of clinical swallow examination and cough reflex testing	05/03/2020	30/10/2020	17/09/2020	30/10/2020	30/10/2020	30/10/2020	05/11/2020	Please select	
33	20/LO/0828	279777	Master protocol of two randomized, double-blind, placebo controlled, multi center, parallel-group studies of dupilumab in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite the use of H1 antihistamine treatment in patients naïve to omalizumab and in patients who are intolerant or incomplete responders to omalizumab	04/08/2020	29/09/2020	09/07/2020	14/10/2020	16/10/2020	16/10/2020		Neither	The study nationally is struggling to recruit its first patient, due to a 4 month washout period and short recruitment period. However, this has now been extended and we hope to have the first patient soon. Patient population for this condition and relevant inclusion/exclusion criteria is small
34	20/EE/0170	1003070	Multicenter, randomized, placebo controlled, double-blind, parallel group, dose-finding Phase 2 study to evaluate the efficacy and safety of BAY 2433334 in patients following an acute myocardial infarction	28/09/2020	28/09/2020	29/07/2020	13/10/2020	16/10/2020	16/10/2020	26/11/2020	Please select	
35	20/YH/0231	284781	A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH DIABETIC MACULAR EDEMA	02/10/2020	20/10/2020	10/09/2020	20/10/2020	20/10/2020	21/10/2020	29/10/2020	Please select	
36	19/EE/0362	272768	A Randomised Multiple Centre Trial of Conservative versus Liberal Oxygenation Targets in Critically Ill Children (Oxy-PICU)	15/10/2020	15/10/2020	23/12/2019	20/10/2020	21/10/2020	21/10/2020	29/10/2020	Please select	
37	20/HRA/4788	288786	A Phase 2/3, Randomized, Placebo-Controlled, Double-Blind Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MK-4482 in Non-Hospitalized Adults with COVID-19	12/10/2020	19/10/2020	05/10/2020	20/10/2020	20/10/2020	20/10/2020	29/10/2020	Please select	
38	19/LO/1652	271917	Phase 3, open-label, single arm study to evaluate efficacy and safety of FIX gene transfer with PF-06838435 (rAAV-Spark100-hFIX-Padua) in adult male participants with moderately severe to severe hemophilia B (FIX:C<2%) (BeneGene-2)	29/10/2020	30/10/2020	28/01/2020	09/11/2020	09/11/2020	10/11/2020		Neither	Newcastle was the infusion site for a patient being recruited at Glasgow. The reason for delay of a patient entering the study, was due to the escalating COVID pandemic and in the intervening time things have improved and Glasgow have been able to set up to perform the infusion themselves
39	20/SC/0027	271232	A Long-term Follow-up Study of Patients in the Clinical Trials for Spinal Muscular Atrophy Receiving AVXS-101	30/03/2020	13/10/2020	06/04/2020	11/11/2020	17/11/2020	17/11/2020		Sponsor	Delays to recruitment have been caused by the sponsor confirming the finer details of an amendment
40	20/NW/0310	267092	A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease (CVD).	14/11/2019	12/10/2020	24/09/2020	04/11/2020	04/11/2020	04/11/2020	04/12/2020	Please select	

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41	10/H0803/121	53663	Genetic Linkage Evaluation in Inherited Cardiac Conditions	30/06/2020	09/07/2020	08/01/2020	19/11/2020	20/11/2020	20/11/2020	10/02/2021	Neither	Initial set up was suspended due to COVID-19. No patients were identified until February 2021 due to the strict inclusion criteria
42	19/LO/0213	256261	A Phase 1 Trial of the combination of PS101-Mediated Acoustic Cluster Therapy (ACT) with Chemotherapy for the Treatment of Liver Metastasis in Patients with Solid Tumours with an Expansion Cohort in Metastatic Colorectal and Pancreatic Cancer	16/10/2020	20/10/2020	07/05/2019	22/10/2020	22/10/2020	03/11/2020		Neither	This study is not formally open yet at our site, as COVID has delayed Marsden NHS finishing the first bit
43	20/YH/0317	288552	A 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	17/09/2020	18/11/2020	10/11/2020	19/11/2020	20/11/2020	20/11/2020	01/12/2020	Please select	
44	19/NE/0310	263546	A Phase IIb double-blind, randomised, placebo-controlled, multi-centre, confirmative three-way cross-over study on cognitive function with two doses of KH176 in subjects with a genetically confirmed mitochondrial DNA tRNA ^{Leu} (UUR) m.3243A>G mutation	26/10/2020	26/10/2020	31/03/2020	18/12/2020	30/12/2020	30/12/2020	17/03/2021	Both	Initial delays were caused by contacting problems within the NHS and Sponsor provider. Considerable delays to recruitment were due to facilitation of tests at site and then prolonged wait times between screening and return of investigational results to validate proceeding to dosing
45	19/LO/1926	274398	A Phase 1/2 Open Label Study to Assess the Safety and Efficacy of UCB6114 Administered Intravenously to Participants with Advanced Solid Tumors	11/02/2020	17/11/2020	19/02/2020	08/12/2020	09/12/2020	09/12/2020	02/03/2021	Neither	As this study is a phase I dose finding study and first allocated slots on a cohort were not until the site opened. The cohorts were slow for the first 'sentinel' patient and it was not Newcastle's turn to treat first, causing delays to the first recruit at this site
46	20/LO/0731	279972	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Prurigo Nodularis	13/05/2020	25/11/2020	25/06/2020	16/12/2020	16/12/2020	17/12/2020		NHS Provider	Delays to recruitment has been caused by the loss of a research nurse and the study needs two. A nurse has been employed and will start with the study team in the near future
47	20/SC/0031	275229	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis	27/11/2020	27/11/2020	26/06/2020	16/12/2020	17/12/2020	17/12/2020		NHS Provider	Staff capacity issues caused delays in receiving the sponsor's green light to commence recruitment
48	20/EE/0118	283014	COG-UK HOCI study	09/09/2020	07/12/2020	15/06/2020	07/12/2020	07/12/2020	07/12/2020	15/12/2020	Please select	
49	20/EM/0142	282923	Phase IIb Multi-Center, Randomised, Partial-Blind Parallel Cohort Study to Assess the Efficacy and Safety of Treatment with GSK3228836 in Participants with Chronic Hepatitis B Virus (B-Clear)	15/09/2020	25/11/2020	16/07/2020	10/12/2020	14/12/2020	14/12/2020	21/01/2021	Please select	
50	18/WM/0207	239150	TWIST – Trial of Wound drain In Surgical site infection in kidney Transplant	15/10/2020	15/10/2020	15/11/2018	24/11/2020	01/12/2020	01/12/2020	06/01/2021	Sponsor	Contracting delays within sponsor company

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51	20/WM/0054	264593	CRAFFT – Children’s Radius - Acute Fracture Fixation Trial: A multi-centre prospective randomised non-inferiority trial of surgical reduction versus non-surgical casting for displaced distal radius fractures in children.	16/10/2020	16/12/2020	16/04/2020	18/12/2020	18/12/2020	18/12/2020	20/03/2021	Neither	Recruitment was delayed due to COVID and fewer than usual children’s fractures have been seen this year due to children not playing out due to the pandemic
52	20/NE/0032	273692	A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF ATEZOLIZUMAB PLUS CARBOPLATIN AND ETOPOSIDE WITH OR WITHOUT TIRAGOLUMAB (ANTI-TIGIT ANTIBODY) IN PATIENTS WITH UNTREATED EXTENSIVE-STAGE SMALL CELL LUNG CANCER	07/09/2020	01/10/2020	28/07/2020	09/10/2020	09/10/2020	09/10/2020		Neither	A change in population due to COVID 19 (patients presenting with more advanced disease and poorer performance status) have caused delays to recruitment
53	20/LO/0453	1003010	A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF BIMEKIZUMAB IN STUDY PARTICIPANTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA	15/09/2020	15/09/2020	29/04/2020	27/10/2020	28/10/2020	28/10/2020		NHS Provider	Contracting delays within the Trust. Recruitment delays have been caused by the loss of a research nurse and the study needs two. A research nurse has been employed and will start with the study team in the near future
54	18/SW/0130	246372	Prospective Evaluation of Thin-strut Biodegradable Polymer-coated Supraflex Sirolimus-Eluting Stents in an All-comers Patient Population (S-FLEX UK-II)	16/05/2018	08/12/2020	29/06/2018	11/01/2021	12/01/2021	13/01/2021	26/01/2021	Please select	
55	19/NW/0571	261307	An adaptive, Phase 2 randomised double-blind, placebo-controlled multi-centre study to evaluate the safety and efficacy of multiple LOU064 doses in patients with moderate to severe Sjögrens syndrome (LOUISSe)	24/09/2019	16/12/2020	06/01/2020	18/12/2020	18/12/2020	11/01/2021		NHS Provider	There was delays with the pharmacy green light and the Part 1 cohort needed to have completed recruitment before Newcastle were able to start with this study cohort.
56	19/LO/0712	257246	IP4- CHRONOS: Comparative Health Research Outcomes of NOvel Surgery in Prostate Cancer	08/01/2021	08/01/2021	07/08/2019	25/01/2021	25/01/2021	25/01/2021		Neither	This is a difficult study to recruit to as two of the three treatments are available outside the trial and patients have quite often had strong opinions about their treatment
57	20/SC/0223	279425	Long-term Safety and Tolerability Study of Limeribat for the Treatment of Cholestatic Pruritus in Participants with Primary Biliary Cholangitis	14/12/2020	14/12/2020	08/07/2020	15/01/2021	25/01/2021	25/01/2021	19/03/2021	Neither	Set up was initially delayed due to COVID-19 however, once Newcastle received the green light on 25/02/2021 study information was sent out to patients. As soon as consent was received staff booked their screening and Newcastle recruited the first 2 patients in the UK on 19/03/2021
58	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	07/09/2020	08/12/2020	23/07/2020	21/01/2021	21/01/2021	25/01/2021		Sponsor	Initial delays were caused by contracting delays with the sponsor. The research team are also waiting for IP shipment. Once the IP has been acknowledged in IWRS the sponsor will activate Newcastle to begin recruitment

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59	20/NW/0383	287807	A Phase 3 Randomized, Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Remdesivir (GS-5734™) Treatment of COVID-19 in an Outpatient Setting	22/12/2020	22/12/2020	23/10/2020	22/01/2021	22/01/2021	25/01/2021		Sponsor	This COVID-19 Study was discontinued by sponsor in light of recent advances, the primary unmet need for patients outside of the hospital setting is for convenient, effective therapies that can be easily administered at home.
60	20/SC/0303	1003379	A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Participants with a diagnosis of Chronic Obstructive Pulmonary Disease and a history of Chronic Bronchitis with a History of Moderate or Severe Acute Exacerbations Receiving Standard of Care Maintenance Therapy	22/12/2020	22/12/2020	09/10/2020	21/01/2021	22/01/2021	22/01/2021		Both	Initial delays were caused by post SIV set up issues with regards to study equipment. Then staff shortages have also impacted on the studies ability to recruit patients during the relevant period
61	20/WM/0220	285844	A Phase Ib/IIa, randomized, double-blind placebo-controlled, multicenter adaptive design clinical trial to evaluate the immune signature of the treatment with the Imotope™ IMCY-0098 and its effect on the preservation of beta-cell function in young adult and adolescent patients with a recent onset Type 1 diabetes	30/11/2020	30/11/2020	11/09/2020	08/01/2021	08/01/2021	25/01/2021	11/03/2021	Neither	This is a trial of a very bespoke immunotherapy for people with newly diagnosed Type 1 diabetes age 18-45. This means finding eligible subjects is a challenge. People are diagnosed with Type 1 diabetes - about 3 patients per month. The eligibility then requires them to have a specific antibody profile and the correct genetic type.
62	20/NE/0250	284888	A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination with Ruxolitinib Versus Best Available Therapy in Subjects with Relapsed/Refractory Myelofibrosis	30/10/2020	09/12/2020	27/11/2020	21/12/2020	21/12/2020	07/01/2021		Neither	This study has a strict inclusion criteria as the main requirement is for platelets above 100. No patient have been identified
63	20/HRA/5205	289098	A PHASE I/II RANDOMIZED, TWO PARTS, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND IMMUNOGENICITY OF AN INACTIVATED, ADJUVANTED SARS-COV-2 VIRUS VACCINE CANDIDATE (VLA2001), AGAINST COVID-19 IN HEALTHY INDIVIDUALS	21/12/2020	21/12/2020	16/12/2020	02/01/2021	04/01/2021	04/01/2021	06/01/2021	Please select	
64	20/NE/0253	288479	COVID-NURSE: evaluation of the effects of a COVID-specific fundamental nursing care protocol compared to care as usual on experience of care for non-invasively ventilated patients in hospital with the SARS-CoV-2 virus: a randomised controlled trial.	05/01/2021	11/01/2021	11/11/2020	12/01/2021	12/01/2021	13/01/2021		Sponsor	The remote SIV did not happen until 3rd March 2021. The study opened to recruitment on 22nd March and the team are actively looking for recruits
65	20/HRA/5234	290965	A randomised, double-blind, placebo-controlled, Phase III trial to determine the efficacy and safety of inhaled SNG001 for the treatment of patients hospitalised due to moderate COVID-19	14/01/2021	25/01/2021	09/11/2020	29/01/2021	29/01/2021	29/01/2021	15/02/2021	Please select	

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66	19/SC/0094	240646	Intravenous immunoglobulin and intravenous methylprednisolone as optimal induction treatment in CIDP	23/11/2020	23/11/2020	16/05/2019	05/02/2021	08/02/2021	08/02/2021		Sponsor	Initial delays were caused by sponsor query resolutions. This study deals with rare patients and none have been identified that meet the strict eligibility criteria'
67	19/LO/1892	272434	A multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial, investigating the efficacy, safety, and tolerability of continuous subcutaneous ND0612 infusion in comparison to oral IR-LD/CD in subjects with Parkinson's disease experiencing motor fluctuations (BouNDless)	13/09/2019	21/01/2021	21/01/2020	05/02/2021	09/02/2021	09/02/2021		Sponsor	Delayed by sponsor because of freezer and used IMP vials and their storage
68	19/NW/0135	252254	An International Randomised Clinical Trial of Therapeutic Interventions with the Potential to Improve Outcome in Adults with Acute Myeloid Leukaemia and High Risk Myelodysplasia Undergoing Allogeneic Stem Cell Transplantation	23/03/2020	14/01/2021	17/05/2019	20/01/2021	23/02/2021	24/02/2021		Neither	To be eligible for this trial patients have to have a specific diagnosis and donor combination. The relatively small number of allogeneic transplants Newcastle perform means there will always be peaks and troughs of eligible patients. The first person approached declined the trial.
69	20/NW/0177	1003027	Phase 3b Open-Label, Multicenter, Safety Study of BIIB037 (aducanumab) in Subjects with Alzheimer's disease Who Had Previously Participated in the Aducanumab Studies 221AD103, 221AD301, 221AD302 and 221AD205.	20/04/2020	20/01/2021	12/06/2020	05/02/2021	05/02/2021	05/02/2021		Please select	
70	20/EM/0089	278775	A PHASE IB, OPEN-LABEL, NON-RANDOMIZED, MULTICENTER STUDY EVALUATING THE SAFETY, PHARMACOKINETICS, AND EFFICACY OF MOSUNETUZUMAB IN COMBINATION WITH LENALIDOMIDE OR RO7082859 IN COMBINATION WITH LENALIDOMIDE OR RO7082859 IN COMBINATION WITH OBINUTUZUMAB PLUS LENALIDOMIDE IN PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA	10/08/2020	22/01/2021	30/07/2020	29/01/2021	29/01/2021	01/02/2021		Please select	
71	20/NW/0300	285728	A Phase 3, randomized, double-blind, efficacy and safety study comparing SAR442168 to placebo in participants with nonrelapsing secondary progressive multiple sclerosis (HERCULES)	18/08/2020	16/12/2020	15/09/2020	04/02/2021	04/02/2021	05/02/2021		Neither	Set up has been delayed due to COVID-19
72	20/LO/0031	266400	Perinatal and 2 year neurodevelopmental outcome in late preterm fetal compromise: the TRUFFLE 2 Randomised Trial	14/09/2020	18/01/2021	04/02/2020	08/02/2021	03/02/2021	09/02/2021		Please select	
73	20/EM/0173	281569	Tapering of Biologics in Inflammatory Arthritis Patients in Remission	16/10/2020	10/11/2020	31/07/2020	19/02/2021	25/02/2021	25/02/2021		Sponsor	Sponsor contracting delays due to financial aspects

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74	20/LO/1128	288114	A Phase 3, Multicenter, Randomized, Efficacy Assessor-Blinded Study of Risankizumab Compared to Ustekinumab for the Treatment of Adult Subjects With Moderate to Severe Crohn's Disease Who Have Failed Anti-TNF therapy	05/02/2021	05/02/2021	03/12/2020	16/02/2021	17/02/2021	17/02/2021		Please select	
75	20/NE/0172	275551	A phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of PF-06939926 for the treatment of Duchenne muscular dystrophy	16/11/2020	29/01/2021	15/10/2020	04/02/2021	04/02/2021	04/02/2021	22/03/2021	Please select	
76	19/LO/0911	263607	A Phase 1/2 trial on the safety, tolerability, pharmacokinetics, pharmacodynamics and exploratory efficacy of DYN101 in patients ≥ 16 years of age with centronuclear myopathies caused by mutations in DNM2 or MTM1.	26/02/2021	26/02/2021	08/08/2019	24/03/2021	25/03/2021	25/03/2021		Please select	
77	20/SC/0007	264068	A PHASE I/II, MULTICENTER, OPEN-LABEL, MULTI-ARM STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PRELIMINARY ACTIVITY OF IDASANUTLIN IN COMBINATION WITH EITHER CHEMOTHERAPY OR VENETOCLAX IN THE TREATMENT OF PEDIATRIC AND YOUNG ADULT PATIENTS WITH RELAPSED/REFRACTORY ACUTE LEUKEMIAS OR SOLID TUMORS	11/02/2021	11/02/2021	21/02/2020	23/03/2021	23/03/2021	23/03/2021		Please select	
78	19/YH/0379	251669	A multi-stage randomised trial of durvalumab (Medi4736) with chemoradiotherapy with 5-fluorouracil and mitomycin C in patients with muscle-invasive bladder cancer	11/03/2020	28/01/2021	07/02/2020	03/03/2021	05/03/2021	11/03/2021		Please select	
79	20/YH/0178	283168	A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with Teriflunomide, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety.	11/06/2020	26/02/2021	29/07/2020	18/03/2021	19/03/2021	19/03/2021		Please select	
80	20/SC/0288	281708	FORTIS: A Phase 1/2, Open-Label, Ascending-Dose Clinical Study to Evaluate the Safety and Preliminary Efficacy of AT845, an AAV8-Delivered Gene Transfer Therapy in Patients with Late Onset Pompe Disease	04/09/2020	05/03/2021	15/01/2021	19/03/2021	23/03/2021	23/03/2021		Please select	

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81	18/LO/0045	233362	A PHASE Ib/II, OPEN-LABEL, MULTICENTER, RANDOMIZED UMBRELLA STUDY EVALUATING THE EFFICACY AND SAFETY OF MULTIPLE IMMUNOTHERAPY-BASED TREATMENT COMBINATIONS IN PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (MORPHEUS-LUNG)	08/09/2020	12/02/2021	08/02/2018	25/03/2021	30/03/2021	30/03/2021		Sponsor	Contracting delays with sponsor company
82	20/YH/0280	282001	A platform study of DNA damage response inhibitors in combination with conventional radiotherapy in non small cell lung cancer	27/10/2020	25/02/2021	06/11/2020	12/03/2021	16/03/2021	17/03/2021		Please select	
83	20/WA/0121	276396	British Heart Foundation Randomised Clinical Trial of Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI)	11/11/2020	05/02/2021	20/05/2020	09/03/2021	09/03/2021	11/03/2021		Please select	
84	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 three-vessel coronary artery disease: Multivessel TALENT.	16/11/2020	22/02/2021	12/02/2021	25/03/2021	25/03/2021	25/03/2021		Please select	
85	19/LO/1866	270431	PlasmaLyte Usage and assessment of kidney Transplant Outcomes in children: the PLUTO trial	12/11/2020	17/12/2020	22/12/2019	19/01/2021	16/03/2021	16/03/2021		Neither	Set up was suspended due to COVID-19
86	20/WA/0028	272436	Post-Market Registry in Europe for the Use of CardioCel®, CardioCel® Neo and CardioCel® 3D	04/12/2020	29/01/2021	17/03/2020	12/03/2021	16/03/2021	17/03/2021		Sponsor	Contracting delays with sponsor company
87	20/EM/0284	288568	A Phase IIb Multi-Center, Randomised, Open Label Study to Assess the Efficacy and Safety of Sequential Treatment with GSK3228836 followed by Pegylated Interferon Alpha 2a in Participants with Chronic Hepatitis B Virus (B-Together)	30/12/2020	26/02/2021	22/12/2020	15/03/2021	17/03/2021	17/03/2021		Please select	
88	18/LO/2033	252294	When to Induce Labour to Limit risk in pregnancy hypertension – a multicentre, randomised controlled trial	11/01/2021	23/02/2021	10/01/2019	08/03/2021	08/03/2021	11/03/2021		Please select	
89	20/EE/0239	281697	A Prospective, Multicenter, Long-Term Study to Assess the Safety and Efficacy of Nemolizumab (CD14152) in Subjects with Prurigo Nodularis	12/01/2021	05/03/2021	29/01/2021	15/03/2021	16/03/2021	17/03/2021		Please select	
90	20/NS/0128	276718	Clinical evaluation of an automated language transcription and analysis app to assist speech and language therapists with clinical decision making in the evaluation of developmental language disorders	12/01/2021	22/01/2021	08/01/2021	03/03/2021	12/03/2021	12/03/2021		NHS Provider	Local Capacity and Capability review delays
91	20/WA/0203	281292	POLARx Cardiac Cryoablation system Post Market Clinical Follow-up study	02/02/2021	18/03/2021	10/08/2020	26/03/2021	29/03/2021	29/03/2021		Please select	

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92	20/NE/0178	269661	EXercise to Prevent frailty and Loss Of independence in insulin treated older people with DiabetEs: The EXPLODE Trial	04/06/2018	11/11/2020	14/08/2020	18/02/2021	25/02/2021	25/02/2021		Neither	This study has been delayed due to covid-19 restrictions impacting on study timelines and staff availability. We anticipate that the first participant will be recruited this month
93	19/LO/0236	230338	The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial - The EFFORT Trial	19/09/2019	02/10/2020	05/07/2019	02/02/2021	03/02/2021	03/02/2021		Both	Initial delays were caused by sponsor and trust over contracting problems. No patients has been seen who was suitable for the study
94	20/LO/0676	273137	Evaluation of Efficacy, Safety and Tolerability of NGM282 (Aldafermin) in a Phase 2b, Randomized, Double-blind, Placebo-controlled, Multi-center Study in Subjects with Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (ALPINE 4)	07/05/2020	10/12/2020	13/07/2020	23/02/2021	22/02/2021	25/02/2021		Sponsor	Initial delays were caused by contracting delays with the sponsor. This study deals with a rare disease and has a strict inclusion criteria