

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	20/LO/1107	258344	A pilot study to compare static night time Ankle Foot Orthosis (AFO) with Contracture Control Device (CCD) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD).	01/04/2021	01/04/2021	01/03/2021	20/04/2021	21/04/2021	21/04/2021	06/05/2021	Please select	
2	21/SC/0119	297443	A single-blind, randomised, phase II UK multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules – Stage 2	24/03/2021	13/04/2021	12/04/2021	15/04/2021	16/04/2021	16/04/2021	20/04/2021	Please select	
3	21/SS/0013	271797	Pain Relief in Major Amputation (PRIMA): A randomised clinical trial comparing pre-incision 'single-shot' nerve block and continuous peri-neural catheter for patients undergoing a major lower limb amputation	30/04/2021	13/05/2021	15/03/2021	13/05/2021	14/05/2021	14/05/2021	12/07/2021	Please select	
4	20/NE/0283	286210	An Open-Label, Randomized, Controlled, Phase 2 Study to Evaluate the Safety and Efficacy of Pegcetacoplan in the Treatment of Post Transplant Recurrence of C3G or IC-MPGN	27/07/2020	26/04/2021	04/02/2021	13/05/2021	13/05/2021	14/05/2021	22/11/2021	Neither	This study is looking into an ultra rare disease and for this reason, no patient presented to the team until November who fitted the eligibility criteria
5	21/NE/0005	277964	The effect of residual beta-cell function on the glucose-lowering potential of mealtime whey protein supplementation in people with diabetes.	01/09/2020	04/05/2021	19/02/2021	19/05/2021	19/05/2021	19/05/2021		NHS Provider	Recruitment has been delayed due to staff illness
6	20/NE/0270	286609	Phase 1/2a Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination with Talazoparib in Advanced Solid Tumors with ATR inhibitor Sensitizing Mutations	26/08/2020	09/04/2021	22/12/2020	07/05/2021	10/05/2021	10/05/2021	18/05/2021	Please select	
7	20/WM/0195	268363	A multi-centre phase II trial of GvHD prophylaxis following unrelated donor stem cell transplantation comparing Thymoglobulin vs. Calcineurin inhibitor or Sirolimus-based post-transplant cyclophosphamide	20/11/2020	29/04/2021	25/09/2020	21/05/2021	24/05/2021	24/05/2021		NHS Provider	Delays to recruitment have been caused by complications within set up from Pharmacy
8	20/LO/1307	291610	A multi-center, randomized, double-blind, placebo-controlled, parallel group, phase III study to evaluate the efficacy and safety of LNP023 in primary IgA nephropathy patients	20/04/2021	20/04/2021	08/02/2021	27/05/2021	28/05/2021	28/05/2021		Neither	No patients have been identified who meet the eligibility criteria

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
9	20/SC/0448	290709	Community participants with COPD or bronchiectasis and at risk of Respiratory Viral Infections including SARS-CoV-2: An open-label, multicentre feasibility study of an inhaled nitric oxide generating solution (RESP301)	14/04/2021	14/04/2021	18/12/2020	06/05/2021	07/05/2021	07/05/2021	25/01/2022	Sponsor	This study was on hold pending a substantial protocol amendment
10	21/LO/0056	1003503	Interventional, randomized, double-blind, parallel-group, placebo-controlled delayed-start study to evaluate the efficacy and safety of eptinezumab in patients with episodic Cluster Headache (eCH).	11/01/2021	06/05/2021	25/02/2021	24/05/2021	24/05/2021	24/05/2021	27/08/2021	NHS Provider	Pharmacy green light was not given until the middle of August 2021 and the first patient was consented on 27th August 2021
11	21/WA/0008	283679	A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, ACTIVE COMPARATORCONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FARICIMAB IN PATIENTS WITH MACULAR EDEMA SECONDARY TO CENTRAL RETINAL OR HEMIRETINAL VEIN OCCLUSION	23/02/2021	20/04/2021	26/03/2021	21/05/2021	21/05/2021	21/05/2021	17/06/2021	Please select	
12	20/EM/0237	266746	Acceptance and Commitment Therapy for Young Brain Tumour Survivors: An Acceptability and Feasibility Trial	22/03/2021	29/04/2021	24/11/2020	14/05/2021	14/05/2021	14/05/2021	11/06/2021	Please select	
13	21/YH/0071	295903	Phase 2/3, Placebo-Controlled, Randomized, Observer-Blinded, Study to Evaluate to the Safety, Tolerability and Immunogenicity of SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) against COVID-19 IN Healthy Pregnant Women 18 years of Age and Older.	24/03/2021	25/05/2021	21/04/2021	25/05/2021	25/05/2021	25/05/2021	24/06/2021	Please select	
14	21/NW/0125	294164	A RANDOMIZED, OBSERVER-BLIND, CONTROLLED, SUPERIORITY STUDY TO COMPARE THE IMMUNOGENICITY AGAINST COVID-19, OF VLA2001 VACCINE TO AZD1222 VACCINE, IN ADULTS	03/03/2021	30/04/2021	20/04/2021	06/05/2021	07/05/2021	07/05/2021	10/05/2021	Please select	
15	21/WA/0066	253665	A randomised crossover design study comparing the pharmacokinetics and pharmacodynamics of two single oral doses of aspirin (75 mg v150mg) in pregnant women at risk of pre-eclampsia.	07/08/2018	23/06/2021	30/03/2021	23/06/2021	25/06/2021	25/06/2021	22/07/2021	Please select	
16	19/SC/0599	270649	A Phase 1b Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in Combination with Nivolumab in Subjects with Advanced Solid Tumours	26/04/2021	26/04/2021	03/03/2020	09/06/2021	15/06/2021	15/06/2021	03/08/2021	Sponsor	Set up was delayed as the contracting team had to wait for sponsor to sign. No patients were identified until August 2021 that met the eligibility criteria

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
17	21/NE/0020	275595	A pragmatic, multicentre, placebo-controlled, 3-arm, double-blinded, randomised controlled trial, incorporating an internal pilot, to determine the role of bronchodilators in preventing exacerbations of bronchiectasis	11/11/2019	14/06/2021	10/03/2021	14/06/2021	14/06/2021	17/06/2021	22/09/2021	Sponsor	Study was delayed recruiting their first patient due to confirmation from sponsor of study opening at site (Greenlight)
18	19/LO/1585	263041	Compression Hosiery to Avoid Post-Thrombotic Syndrome	17/12/2019	03/06/2021	24/10/2019	24/05/2021	25/06/2021	29/06/2021		NHS Provider	Recruitment has been difficult due to staffing issues
19	21/LO/0186	286735	Effects of tele-rehabilitation multimodal lifestyle intervention on function capacity, cardiovascular health and quality of life inpatients with peripheral artery disease from low socioeconomic areas: a pilot randomized controlled trial Telehealth EXercise Training in peripheral arterial disease –The TEXT-PAD study	01/07/2020	06/05/2021	22/04/2021	05/08/2020	11/06/2021	11/06/2021	15/09/2021	NHS Provider	Recruitment was delayed due to staff issues due to COVID and long term sick
20	20/NW/0340	1003335	A PHASE IIIB MULTICENTER, RANDOMIZED, DOUBLE-BLIND, CONTROLLED STUDY TO EVALUATE THE EFFICACY, SAFETY AND PHARMACOKINETICS OF A HIGHER DOSE OF OCRELIZUMAB IN ADULTS WITH PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS	22/09/2020	19/05/2021	18/09/2020	19/05/2021	20/05/2021	08/06/2021		Sponsor	The research team are currently awaiting Doctor training before they are able to gain green light from the sponsor
21	20/WS/0057	277361	Erythropoietin and Darbepoetin in Neonatal Encephalopathy (EDEN) study	20/10/2020	19/05/2021	27/05/2020	01/06/2021	02/06/2021	02/06/2021	21/11/2021	NHS Provider	The research team initially were unable to recruit to EDEN due to the pharmacy production team not being ready to disperse the drug
22	21/EM/0041	281071	Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge: The Hummingbird Study	13/11/2020	20/05/2021	06/04/2021	01/06/2021	01/06/2021	01/06/2021	08/06/2021	Please select	
23	20/YH/0300	287046	A Prospective, Multi-Center Study of the Braive™ Growth Modulation System When Used in the Treatment of Pediatric Patients Diagnosed with Juvenile or Adolescent Idiopathic Scoliosis (BRAIVE IDE Study)	26/04/2021	09/06/2021	04/01/2021	11/06/2021	11/06/2021	14/06/2021	12/08/2021	Please select	
24	21/WM/0013	283141	Hysteroscopic Excision of Leiomyoma and Polyp in Infertility - two randomised controlled trials	21/05/2021	07/06/2021	10/02/2021	09/06/2021	09/06/2021	17/06/2021	18/01/2022	Neither	Recruitment delays were due to low number of patients are presenting at the hospital who met the strict eligibility criteria

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
25	21/SC/0200	300677	A Phase II/III Partially Double-Blinded, Randomised, Multinational, Active-Controlled Study in Both Previously Vaccinated and Unvaccinated Adults Ages 30 and Above to Determine the Safety and Immunogenicity of AZD2816, a Vaccine for the Prevention of COVID-19 Caused by Variant Strains of SARS-CoV-2	15/06/2021	29/06/2021	22/06/2021	29/06/2021	29/06/2021	29/06/2021	07/07/2021	Please select	
26	21/YH/0026	289207	The HistoSonics System for treatment of primary and metastatic liver tumors using histotripsy.	16/09/2020	24/05/2021	16/04/2021	24/05/2021	25/05/2021	09/06/2021	08/07/2021	Please select	
27	20/LO/0821	281982	AN OPEN-LABEL, MULTICENTER, ROLLOVER STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF LONG-TERM GANTENERUMAB ADMINISTRATION IN PARTICIPANTS WITH ALZHEIMER'S DISEASE	18/08/2020	10/06/2021	23/07/2020	10/06/2021	18/06/2021	18/06/2021	30/06/2021	Please select	
28	19/SC/0112	259372	Adalimumab in Juvenile Idiopathic Arthritis-associated Uveitis Stopping Trial (ADJUST)	04/05/2021	02/06/2021	12/11/2019	10/06/2021	14/06/2021	16/07/2021	23/11/2021	Sponsor	This study did not recruit initially because the machine sent to ophthalmology as part of the study, did not work and this was also a problem at other sites. After many virtual meetings, it was decided with sponsor to use a paper alternative
29	20/EM/0159	278357	Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial (RACER)	16/10/2020	01/07/2021	29/07/2020	01/07/2021	09/07/2021	09/07/2021	02/11/2021	Neither	No patient was identified initially due to the way the study logistics work as the team will only approach patients who are attending a pre-op clinic – The team had 242 patients on the waiting list and the process of screening and checking when pre-op appointments was quite time consuming and made more difficult due to reduced staffing
30	20/SC/0299	283235	A Phase 1b/2, Open-Label Trial to Assess the Safety and Preliminary Efficacy of Epcoritamab (GEN3013; DuoBody® CD3xCD20) in Combination with Other Agents in Subjects with B-cell Non-Hodgkin Lymphoma	09/12/2020	16/06/2021	01/10/2020	15/07/2021	19/07/2021	19/07/2021		NHS Provider	The research team are yet to recruit to this study due to a significant nursing capacity issue within the team, which is related to maternity leave and long term sickness of our chemotherapy trained nursing staff

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
31	21/FT/0003	291436	Randomised, double-blind, placebo-controlled, parallel group Phase 3 study to evaluate the efficacy, safety, and tolerability of SAR440340/REGN3500/itepekimab (anti-IL-33 mAb) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD)	25/01/2021	28/06/2021	15/03/2021	05/07/2021	06/07/2021	06/07/2021	30/09/2021	Both	Delays were caused in receiving sponsor green light, due to a difficulties in arranging a mutual agreeable SIV date. The team were also waiting for the PI and Sub-PI to complete training on third party vendors before sponsor would sign off the site as active
32	21/ES/0041	1003675	A Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Ravulizumab in Adult Participants Who Have Thrombotic Microangiopathy Associated With a Trigger	24/02/2021	01/07/2021	12/05/2021	04/07/2021	05/07/2021	06/07/2021		Neither	This study deals with a rare life threatening disease. No eligible patients have been identified
33	21/NW/0017	291746	BabyBreathe Trial: A randomised controlled trial of a complex intervention to prevent return to smoking postpartum	31/03/2021	05/07/2021	16/03/2021	06/07/2021	06/07/2021	06/07/2021	15/11/2021	Both	After C&C was issued the SIV took far longer than expected to schedule due to AL/Staff availability. As the study relies on the health visitor team to support the trial they needed to be appropriately trained before sponsor would open Newcastle as a site.
34	20/SC/0018	258872	A randomised controlled trial assessing if microsurgical nerve repair offers clinical benefit and cost effectiveness (in terms of patient-reported hand function, sensory recovery and adverse events) over exploration and washout without microsurgical nerve repair in adult patients with recent traumatic digital nerve injury.	14/04/2021	17/06/2021	13/02/2020	01/07/2021	06/07/2021	06/07/2021	31/01/2022	Neither	The team only saw one appropriate patient since opening the study and they declined to take part. The team have noted that over the last 2 months, they have not seen the normal number of patients with digital nerve injuries. The team eventually recruited their first patient in January
35	21/HRA/0489	294480	OCTAVE: Observational Cohorts Trial - T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2	24/05/2021	23/06/2021	12/02/2021	05/07/2021	06/07/2021	06/07/2021	16/08/2021	Please select	

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
36	20/EE/0077	278155	A phase 3 multicentre, double-blind, randomised, placebo-controlled study to evaluate the efficacy, safety, and tolerability of Rozanolixizumab in adult study participants with persistent or chronic primary immune thrombocytopenia (ITP)	05/05/2020	08/06/2021	20/04/2020	11/08/2021	24/08/2021	24/08/2021		Both	Delays in set up and recruitment were caused by Pharmacy production being unable to support the study. The team also had to find an alternative drug prep team and recently the sponsor has decided on a temporary halt of the TP0003 and TP0006 trials to stop recruitment of further trial subjects as of 19-November-2021 for non-safety related reasons
37	20/NW/0470	275219	Metformin to prevent progression of sarcopenia and frailty in older people – a randomised controlled proof of concept trial	10/08/2020	27/07/2021	07/01/2021	11/08/2021	19/08/2021	19/08/2021	16/09/2021	Please select	
38	19/EE/0377	266504	Trial of Ondansetron as a Parkinson's HALLucinations Treatment	26/08/2020	12/07/2021	17/06/2020	19/08/2021	19/08/2021	19/08/2021		NHS Provider	SIV was initially planned for Early September but due to clinical requirements of the PI and Sub-I the SIV was pushed back to October, the study team are actively searching for recruits
39	20/NE/0097	265147	A Randomised Feasibility n-of-1 Trial of Weekly-Interval Red Cell Transfusion in myelodysplastic syndromes	01/07/2019	06/08/2021	18/08/2020	06/08/2021	20/08/2021	20/08/2021	01/10/2021	Please select	
40	20/YH/0232	280105	ATNEC - Axillary management in T1-3N1M0 breast cancer patients with needle biopsy proven nodal metastases at presentation after neoadjuvant chemotherapy	16/11/2020	15/07/2021	22/10/2020	29/07/2021	03/08/2021	03/08/2021	23/09/2021	Please select	
41	21/WM/0017	287442	A Phase 2a/2b Randomized Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Volixibat in Adult Women with Intrahepatic Cholestasis of Pregnancy and Elevated Serum Bile Acid Concentrations (OHANA)	25/03/2021	27/08/2021	08/03/2021	30/08/2021	31/08/2021	31/08/2021		Neither	This is a commercial trial testing a new treatment for pregnant women. The trial has a huge number of exclusion criteria, and a significant proportion of women are declining to participate
42	20/EE/0252	276415	Pharmacological management of seizures post traumatic brain injury (MAST)	31/03/2021	02/06/2021	20/01/2021	20/07/2021	09/08/2021	09/08/2021	20/08/2021	NHS Provider	Delays to confirmation and capacity were caused by staff annual leave after contract was signed and PI wanting to see the first participant on their return from leave

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
43	21/FT/0058	293068	A Phase 1 Study Exploring the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of INCB099318 in Participants With Select Advanced Solid Tumors	22/04/2021	11/08/2021	17/05/2021	19/08/2021	19/08/2021	19/08/2021	18/10/2021	Please select	
44	21/FT/0069	290279	A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy	06/05/2021	29/07/2021	07/07/2021	12/08/2021	16/08/2021	16/08/2021	07/09/2021	Please select	
45	21/WS/0003	286426	COLO-DETECT: A Randomised Controlled Trial of Lesion Detection at Colonoscopy Using the GI Genius™ Artificial Intelligence Platform	18/05/2021	13/08/2021	25/01/2021	16/08/2021	16/08/2021	16/08/2021	03/12/2021	Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population
46	21/NW/0109	1003688	A MULTICENTER, OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AVONELLE-X)	15/06/2021	30/07/2021	18/06/2021	03/08/2021	04/08/2021	04/08/2021	05/08/2021	Please select	
47	18/EM/0190	243165	A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome	08/10/2018	24/08/2021	14/09/2018	08/09/2021	09/09/2021	09/09/2021	16/11/2021	Sponsor	Delays to recruitment were caused by issues with supplies for the infusion. The sponsor only informed the research team at the SIV that they had to source their own stock of the infusion bags/kits and some of the items are not stocked in the trust. They had to liaise with supplies, request quotes from the manufacture and then order the non-stock items. Due to COVID this all took longer than usual

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
48	18/WM/0227	235254	The Carboprost or Oxytocin Postpartum haemorrhage Effectiveness Study. Carboprost vs Oxytocin as the First Line Treatment of Primary Postpartum Haemorrhage; A phase IV, double-blind, double-dummy, randomised controlled trial.	16/08/2019	28/05/2021	28/11/2018	07/09/2021	08/09/2021	08/09/2021		Sponsor	Delays were caused by the sponsor not providing signatures after being chased by governance team over a period of many weeks. Recruitment has been delayed as many of the medical staff within maternity have to be trained and this has been slow due to staff absences due to the pandemic. The research fridge where the IMP is held had to be replaced and the team are in the process of installing a new fridge this taken longer than expected
49	19/SC/0456	266074	A Phase 1b/2 Randomised, Placebo-controlled, Dose-ranging Study to Evaluate Safety, Tolerability and Immunogenicity of a Chimpanzee Adenovirus (ChAdOx1)-vectored Multigenotype High Risk Human Papillomavirus (hrHPV) Vaccine and Modified Vaccinia Ankara (MVA)-vectored Multigenotype hrHPV Vaccine in Women with Low-grade HPV-related Cervical Lesions	23/10/2019	18/08/2021	13/08/2020	13/09/2021	15/09/2021	15/09/2021	15/11/2021	Neither	A number of women received the Patient Information Leaflet, but were not prepared to commit to the time commitment of the study
50	20/SC/0041	275334	Study title: OPTimizaTion of Left MAin PCI with IntravascuLar Ultrasound. The OPTIMAL Randomized Controlled Trial	27/02/2020	06/08/2021	15/06/2020	02/09/2021	02/09/2021	22/09/2021	27/10/2021	Sponsor	Delays to recruitment of first patient were caused by the sponsor not giving green light until 3 weeks after trust approval of the study
51	18/SC/0028	235714	A Phase 1 Multicenter, Open-Label Study to Assess The Safety, Pharmacokinetics And Preliminary Efficacy of CC-92480 in Combination With Dexamethasone in Subjects With Relapsed And Refractory Multiple Myeloma	30/09/2020	02/08/2021	08/03/2018	28/09/2021	28/09/2021	28/09/2021	19/10/2021	Both	Initial finance issues sent to sponsor on 16th August with the contract going back and forth between sponsor and Trust until agreement on 16th September, when final contract was sent to sponsor for signature. Sponsor signed contract on 28th September (contract sent for Trust signature same day)

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
52	19/EE/0228	260350	Sugar or Salt (SOS) trial: Hyperosmolar therapy in traumatic brain injury	16/10/2020	02/08/2021	18/12/2019	15/09/2021	15/09/2021	15/09/2021	29/03/2022	Sponsor	Sponsor delays were caused because they took a long time to sign the contract. No patient was recruited initially because staff, resources and time were diverted to COVID-19 studies. This is a critical care study
53	21/LO/0449	1003652	Randomised controlled trial of plasma cell depletion for severe Graves' disease	29/10/2020	25/08/2021	08/07/2021	08/09/2021	15/09/2021	15/09/2021	11/10/2021	Please select	
54	20/LO/1207	282292	A Double-blind Randomized, Placebo-Controlled Study and Open-label Long Term Extension to Evaluate the Efficacy and Safety of Elafibranor 80 mg in Patients with Primary Biliary Cholangitis with Inadequate Response or Intolerance to Ursodeoxycholic Acid	30/12/2020	24/08/2021	17/02/2021	02/09/2021	03/09/2021	03/09/2021	21/03/2022	Neither	No eligible participants seen initially due to them taking second line drugs that excludes them from the trial. The team are actively searching for participants
55	20/EE/0294	288140	A Phase 3, Randomized, Double-blind, Multicenter, Placebo-Controlled Study of Inebilizumab Efficacy and Safety in IgG4 Related Disease	11/01/2021	30/04/2021	04/02/2021	20/09/2021	21/09/2021	21/09/2021		Sponsor	Sponsor delays with contracting queries. The study team had a patient set to recruit and unfortunately they had a very low titre positive antibody, which meant they were not eligible. The team continue to actively search but unfortunately, this is a rare disease and active /flaring patients have already been treated
56	21/PR/0752	280032	Methodological validation of an intermittent shuttle walking protocol in the context of pulmonary rehabilitation in patients with Chronic Obstructive Pulmonary Disease	20/01/2021	10/09/2021	23/07/2021	13/09/2021	13/09/2021	13/09/2021	21/09/2021	Please select	
57	21/NS/0007	291857	Multi-centre prospective observational cohort study: To assess the performance of single use duodenoscope	19/04/2021	27/07/2021	11/02/2021	01/09/2021	01/09/2021	01/09/2021	01/02/2022	Neither	Eligible patients were sought and one patient who met the criteria initially declined. The team tried very hard to recruit, but were limited due to COVID related factors
58	21/NE/0077	286650	A double-blind, placebo-controlled, study to evaluate the efficacy and safety of 24 weeks treatment with REN001 in patients with Primary Mitochondrial Myopathy (PMM)	21/04/2021	16/08/2021	12/05/2021	16/09/2021	16/09/2021	16/09/2021	08/02/2022	Neither	Recruitment was delayed due to participants expressing interest in the study, then being hesitant to travel long distances to site due to COVID

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
59	19/WA/0019	247285	ROSSINI 2: A Phase III, multi-arm, multi-stage (MAMS) pragmatic, blinded (patient and outcome assessor) multicentre, randomised controlled trial (RCT) with an internal pilot, to evaluate the use of three in-theatre interventions, alone or in combination, to reduce SSI rates in patients undergoing abdominal surgery.	18/06/2021	11/08/2021	01/02/2019	07/09/2021	08/09/2021	08/09/2021	09/09/2021	Please select	
60	21/YH/0033	290847	Breathing Retraining for Asthma Trial of Home Exercises for Teenagers; repurposing, refining and feasibility – Stage 3	01/07/2021	28/07/2021	16/04/2021	03/09/2021	03/09/2021	03/09/2021	03/10/2021	Please select	
61	21/SC/0261	300456	Post-approval follow-up for the COV001 and 002 trials, to determine the long-term safety and character of immunological response to the ChAdOx1 nCoV-19 coronavirus vaccine	10/08/2021	13/09/2021	20/08/2021	14/09/2021	15/09/2021	16/09/2021	23/09/2021	Please select	
62	20/LO/1289	1003429	Efficacy and Safety Study of Vatiquinone for the Treatment of Refractory Epilepsy in Subjects with Mitochondrial Disease	16/12/2020	29/06/2021	20/01/2021	21/07/2021	22/07/2021	22/07/2021	28/09/2021	Both	Delays to recruitment were caused by sponsor sorting out logins for study staff and site files delays. The PI also caused delays as he preferred the study to go active after his annual leave as the cohort of children are hard to recruit over the summer school holidays
63	19/LO/0043	255663	A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C	16/03/2021	09/07/2021	01/03/2019	09/07/2021	12/07/2021	12/07/2021	13/08/2021	Please select	
64	21/WM/0012	288511	A Phase 2, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of the Oral Pan-RAF Inhibitor DAY101 in Pediatric Patients with BRAF-Altered, Recurrent or Progressive Low-Grade Glioma	11/01/2021	18/08/2021	23/03/2021	25/10/2021	27/10/2021	27/10/2021	21/12/2021	Sponsor	Initial delays were caused by the sponsor giving the incorrect invoicing address on the contract. No eligible patient was initially seen during the reporting period
65	20/NE/0243	289044	Double-blind, randomised, placebo-controlled, phase II dose-finding study comparing different doses of RhuDex granules with placebo in the treatment of primary biliary cholangitis	09/02/2021	12/07/2021	07/12/2020	07/10/2021	11/10/2021	11/10/2021	24/01/2022	Sponsor	Delays were caused by sponsors response to financial queries. No patient initially seen fitted the eligibility criteria

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
66	20/WM/0302	276338	Comparing the effectiveness of side-lying sleep positioning to back-lying at reducing oxygen desaturation resulting from Obstructive Sleep Apnoea in infants with cleft palate.	17/02/2021	21/06/2021	22/12/2020	18/10/2021	27/10/2021	27/10/2021		Sponsor	Delays were caused by sponsors not progressing the contract due to lack of study equipment. No patient has been identified that fits the eligibility criteria
67	21/FT/0021	290662	A Phase 1-2 Study of the Safety, Pharmacokinetics, and Activity of ASTX029 in Subjects With Advanced Solid Tumors	19/04/2021	24/08/2021	21/04/2021	12/10/2021	14/10/2021	14/10/2021		Sponsor	Delays were caused by sponsor reviewing the contract. No patient has been seen that fits the eligibility criteria
68	20/SC/0328	287955	Phase I/II Study of the Safety, Pharmacokinetics, and Preliminary Clinical Activity of BT5528 in Patients with Advanced Malignancies Associated with EphA2 Expression	19/04/2021	25/08/2021	09/10/2020	04/10/2021	05/10/2021	05/10/2021	08/03/2022	Sponsor	Delays were caused waiting for the sponsor signature on the contract. No eligible participants was seen initially who fitted the study criteria
69	20/EE/0293	276366	Vitrectomy, subretinal Tissue plasminogen activator and Intravitreal Gas for submacular haemorrhage secondary to Exudative age-Related macular degeneration (TIGER): a phase 3, pan-European, two-group, active-control, observer-masked, superiority, randomised controlled surgical trial.	27/04/2021	15/09/2021	19/02/2021	17/09/2021	06/10/2021	06/10/2021		Sponsor	Study is still awaiting green light from sponsor due to an amendment to the protocol
70	20/NE/0219	284245	A phase IIa efficacy and safety trial with intravenous S95011 in primary Sjögren's Syndrome patients. An international, multicentre, randomised, double-blind, placebo-controlled study.	04/05/2021	04/10/2021	20/10/2020	08/10/2021	14/10/2021	14/10/2021		Sponsor	Study is still awaiting green light from sponsor
71	21/FT/0050	294543	A randomised double-blind placebo-controlled clinical trial investigating the effect and safety of oral semaglutide in subjects with early Alzheimer's disease (EVOKE plus)	10/05/2021	22/09/2021	20/05/2021	08/10/2021	13/10/2021	13/10/2021		Neither	The study team have been unable to recruit as the PET/MR has been out of action due to an act of vandalism in December. The PI and study team are currently exploring other options for the screening requirements in this study.
72	21/WA/0288	277338	Fitness AfteR Oesophagectomy- an external pilot trial of the impact of rehabilitation on quality of life after surgery for oesophageal cancer	04/06/2021	13/10/2021	28/09/2021	14/10/2021	14/10/2021	14/10/2021	11/11/2021	Please select	

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
73	21/EE/0129	296931	Aortic, Peripheral & Venous (APV) PRODUCT SURVEILLANCE REGISTRY (PSR) PLATFORM BASE	24/05/2021	01/10/2021	10/08/2021	05/10/2021	26/10/2021	26/10/2021	22/03/2022	Sponsor	Green light from sponsor was not received until 17/12/21 because of delayed documentation. The team did not find an eligible patient until March 2022
74	21/FT/0090	300783	A randomized, double-blind, head-to-head comparison of dupilumab versus omalizumab in severe Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) and comorbid asthma patients	01/07/2021	28/09/2021	26/08/2021	12/10/2021	13/10/2021	13/10/2021		NHS Provider	The study team are still awaiting Green Light from Pharmacy
75	20/LO/1291	292074	The effect of semaglutide in subjects with non-cirrhotic non-alcoholic steatohepatitis	26/07/2021	18/10/2021	12/02/2021	28/10/2021	29/10/2021	29/10/2021		Sponsor	Study team are still awaiting Green Light confirmation from the sponsor
76	20/SS/0039	277102	Edoxaban for IntraCranial Haemorrhage survivors with atrial fibrillation (ENRICH-AF)	13/08/2021	21/09/2021	03/02/2021	21/10/2021	28/10/2021	28/10/2021		Sponsor	The study did not receive the green light from sponsor until late December. No eligible patient has been seen who fits the study criteria
77	21/LO/0389	296448	TCB008 Gamma Delta T Cell Therapy in COVID-19	25/08/2021	21/10/2021	14/10/2021	29/10/2021	29/10/2021	29/10/2021		Sponsor	Sponsor terminated the study. This was due to the mild symptoms seen with the current Omicron variant of COVID, that meant it was no longer possible to recruit suitable patients
78	21/HRA/3483	303827	A multi-centre randomised controlled trial examining the effects of temporarily suspending low-dose methotrexate treatment for two weeks after SARS-CoV-2 vaccine booster on vaccine response in immunosuppressed adults with inflammatory conditions, including a nested mechanistic sub-study	31/08/2021	24/09/2021	23/08/2021	30/09/2021	07/10/2021	07/10/2021	25/10/2021	Please select	
79	19/YH/0317	265113	Prehabilitation in Elective Patients Undergoing Cardiac Surgery: A Randomised Controlled Trial	02/09/2021	04/10/2021	28/10/2019	05/10/2021	19/10/2021	19/10/2021		NHS Provider	The study has been put on hold because the PI is unavailable at present. Also no patients are coming into hospital for the rehab procedure due to COVID
80	21/EM/0177	292216	Adjunctive Vagus Nerve Stimulation for Improving Neural control of Gait in Parkinson's Disease	17/09/2021	05/11/2021	26/08/2021	12/11/2021	15/11/2021	15/11/2021	17/01/2022	Neither	No eligible patients seen during the reporting period

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
81	21/NE/0083	277408	Control, Fludrocortisone or Midodrine for the treatment of Orthostatic Hypotension: A Randomised Controlled Trial	02/10/2019	25/10/2021	15/06/2021	25/11/2021	26/11/2021	26/11/2021		Neither	Delays to recruitment have been caused by storm damage to the research teams clinical area and led to cancellation of all research clinics. This has now been rectified and the site are actively pre-screening, but there is a high level of ineligibility
82	19/LO/0456	228992	European Proof-of-Concept Therapeutic Stratification Trial of Molecular Anomalies in Relapsed or Refractory Tumours	11/11/2019	24/09/2021	29/05/2019	18/11/2021	26/11/2021	26/11/2021		NHS Provider	Contract signing delays were caused by individual Trust departments. No eligible participants has been identified during this reporting period
83	21/YH/0137	281536	TRANScranial direct current Stimulation for FOCal Refractory epilepsy in Mitochondrial disease (TRANSFORM): delayed-start, randomised, double-blinded, placebo-controlled trial	07/10/2020	01/11/2021	14/09/2021	12/11/2021	16/11/2021	16/11/2021		Neither	This study is a rare disease study and the patient group is very small
84	21/LO/0540	290737	A virtual pathway to improving the efficiency of MRI scanning	05/10/2020	24/11/2021	14/09/2021	24/11/2021	24/11/2021	24/11/2021	23/02/2022	NHS Provider	Delays to recruitment were caused because the team had to relaunch the app and put all the paperwork together manually, due to staff COVID absences
85	21/SC/0017	268864	MultiStem® Administration for Stroke Treatment and Enhanced Recovery Study (MASTERS-2)	03/03/2021	15/09/2021	14/06/2021	18/10/2021	04/11/2021	04/11/2021		Sponsor	Delays were caused by sponsor not signing the contract in time. No patients have been identified who meet the strict eligibility criteria
86	21/EE/0055	1003560	A PHASE IIB, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INTRAVENOUS PRASINEZUMAB IN PARTICIPANTS WITH EARLY PARKINSON'S DISEASE	16/04/2021	11/11/2021	09/03/2021	24/11/2021	17/11/2021	24/11/2021	01/03/2022	Neither	The inclusion/exclusion criteria is very strict. Many patients refused due, to the intense participation involved in the study
87	21/NE/0145	300809	Telehealth exercise for patients with primary liver cancer	01/06/2021	02/11/2021	16/09/2021	03/11/2021	03/11/2021	03/11/2021	22/11/2021	Please select	
88	19/SC/0021	249552	OPTimal TIMing of Anticoagulation after acute ischaemic Stroke: a randomised controlled trial (OPTIMAS Trial)	07/06/2021	08/10/2021	04/04/2019	11/10/2021	12/10/2021	03/11/2021	29/11/2021	Please select	

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
89	20/EE/0127	277059	The HUmeral SHaft fracture trial: A multi-centre prospective randomised superiority trial of surgical versus non-surgical interventions for humeral shaft fractures in patients aged 18 years or older	08/09/2021	01/11/2021	02/06/2020	16/11/2021	26/11/2021	26/11/2021	16/02/2022	NHS Provider	Three eligible patients were identified initially, two declined to participate due to a preference for treatment, and one was missed due to staff shortages
90	21/SC/0310	304450	A single-blind, randomised, phase II multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules in adolescents (COM-COV3)	25/10/2021	05/11/2021	14/09/2021	11/11/2021	11/11/2021	11/11/2021		Sponsor	Sponsor paused recruitment in November in light of changing government policy
91	19/SW/0043	235625	CHIEF-PD (Cholinesterase Inhibitor to prevent Falls in Parkinson's Disease): A phase 3 randomised double-blind placebo-controlled trial of rivastigmine to prevent falls in Parkinson's disease	18/05/2020	12/11/2021	26/07/2019	14/12/2021	17/12/2021	17/12/2021	31/03/2022	Sponsor	Delay confirmation from sponsor of study open and no eligible patient was identified until March 2022
92	21/NE/0084	280025	Obeticholic acid for the Amelioration of Cognitive Symptoms trial- 2	13/11/2019	10/11/2021	03/06/2021	08/12/2021	09/12/2021	09/12/2021	06/01/2022	Please select	
93	20/ES/0034	276977	A two-part phase I study with the antibody-drug conjugate SYD985 in combination with niraparib to evaluate safety, pharmacokinetics and efficacy in patients with HER2-expressing locally advanced or metastatic solid tumours	03/07/2020	29/09/2021	20/04/2020	07/12/2021	10/12/2021	13/12/2021		Both	Support departments approvals were out of date and had to be requested before the study was allocated for set up. Study closed early by sponsor because the drug was found to be too toxic and the study halted on safety grounds before the research team were able to recruit to a slot
94	21/NW/0178	1003810	A phase IIa, randomized, 2-arm parallel-group, placebo-controlled, double-blind, multi-centre trial to evaluate safety, tolerability, anti-inflammatory and cardioprotective effects after intravenous and oral administration of KAND567 in ST-elevation myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention	08/07/2020	25/10/2021	07/07/2021	03/12/2021	06/12/2021	06/12/2021	29/12/2021	NHS Provider	Local capacity and capability review was not completed in time
95	20/ES/0067	1003032	A Multicenter, Randomized, Double-blind, Placebo controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Dapirolizumab Pegol in Study Participants with Moderately to Severely Active Systemic Lupus Erythematosus	18/03/2021	06/06/2021	08/09/2020	01/12/2021	06/12/2021	06/12/2021		NHS Provider	Contacting delays were caused by research team. No eligible participants have been identified

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
96	20/EE/0043	269050	The effectiveness and risks of Treating people with Idiopathic Pulmonary fibrosis with the Addition of Lansoprazole (TIPAL): a randomised placebo-controlled multi-centre clinical trial	04/02/2021	11/11/2021	28/10/2020	25/11/2021	01/12/2021	01/12/2021	23/02/2022	Sponsor	The SIV greenlight process took longer than anticipated and the first suitable patient was not attending clinic until late February. The study design states that patients are approached and consented as part of their standard clinic follow up appointment
97	19/ES/0049	260196	The ADDapt diet in reducing Crohn's disease inflammation - Version 1	29/03/2021	17/11/2021	15/07/2019	14/12/2021	14/12/2021	14/12/2021	24/03/2022	Neither	Patients need to have (mildly) active Crohn's with symptoms and a positive stool test for inflammation, where a step up in medical therapy is not needed/declined and where the patients is willing to have dietary intervention. The research team thought it would be easy to identify this group, but actually it has been quite tough to find patients who meet these criteria's
98	21/FT/0052	292370	A randomized, parallel group, multicentre, multinational, prospective, open-label exploratory study to evaluate the add-on effect of opicapone 50 mg or levodopa 100 mg as first strategy for the treatment of wearing-off in patients with Parkinson's Disease.	07/06/2021	08/11/2021	27/05/2021	17/12/2021	17/12/2021	17/12/2021		Neither	No eligible patients seen during the reporting period
99	21/FT/0082	300630	ZEUS - Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation	09/06/2021	08/12/2021	13/09/2021	16/12/2021	16/12/2021	16/12/2021		Neither	Recruitment delays: The initial screening prior to fully taking part in the study involves a blood test looking at inflammation markers. The criteria for inclusion based on the result of this blood test is very specific and we were made aware by the sponsor company that this contributes to screening fails in well over 50% of all screened patients globally. No patient has been identified who meets this criteria.

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
100	20/NE/0020	277060	A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the 'Your Care Needs You!' intervention to improve safety and experience of care transitions.	22/06/2021	05/11/2021	26/02/2020	30/11/2021	14/12/2021	14/12/2021	24/02/2022	NHS Provider	Due to staffing levels in December and January due to COVID the start date for study recruitment was delayed until the 1st February 2022. The study is not ongoing, and in spite of being hampered by restricted visiting, which has prevented recruitment of patients with reduced mental capacity, recruitment is going well
101	21/NE/0128	289134	A Phase IIIb, open-label, single-arm, single-dose, multicenter study to evaluate the safety, tolerability and efficacy of gene replacement therapy with intravenous OAV101 (AVXS-101) in pediatric patients with spinal muscular atrophy (SMA)	25/06/2021	24/11/2021	05/10/2021	02/12/2021	02/12/2021	02/12/2021	14/12/2021	Please select	
102	21/LO/0035	270373	ARTHRITIS PREVENTION IN THE PRE-CLINICAL PHASE OF RA WITH ABATACEPT (APIPPRA) LONG TERM OUTCOME STUDY: THE ALTO STUDY	15/09/2021	25/10/2021	05/03/2021	03/12/2021	10/12/2021	10/12/2021	28/02/2022	Sponsor	Initial delays were caused by sponsor changing the wording in the contract. Recruitment delays were caused by sponsors not giving the Green Light to open the study until February
103	21/WM/0196	297458	CP340 SUN-Study Investigation of patient benefits with a new supporting ostomy product and support service in patients with a newly stoma formation.	25/10/2021	16/11/2021	03/11/2021	03/12/2021	03/12/2021	03/12/2021	14/01/2022	Please select	
104	19/LO/1064	260639	The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?	29/04/2020	25/10/2021	06/11/2019	07/12/2021	25/01/2022	26/01/2022		Sponsor	Delays were caused by contracting within sponsor company. Recruitment was delayed due to COVID studies being prioritised within the research team
105	19/NE/0110	257719	A randomised, double-blind, placebo-controlled, cross-over trial of zibotentan in microvascular angina	25/08/2020	09/12/2021	04/12/2019	13/12/2021	10/01/2022	10/01/2022	23/03/2022	NHS Provider	Study team were unable to get green light to use the stress test (ECG) facility due to COVID until March 2022
106	21/NE/0100	293565	Acipimox to improve muscle function and sarcopenia – a feasibility study	16/12/2020	10/12/2021	22/07/2021	21/12/2021	05/01/2022	05/01/2022		Sponsor	The Green light was not given by sponsor until the 28th March 2022
107	20/WS/0178	290482	Anaesthesia Choice for Creation of artEriovenouS fiStulae	25/06/2021	22/10/2021	24/05/2021	11/01/2022	11/01/2022	11/01/2022	09/03/2022	NHS Provider	Study approval delays were caused by Finance queries within the Trust. No eligible patient was identified until March 2022

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
108	21/SW/0049	283345	Early Laser for Burn Scars (ELABS) - A multi-centre randomised, controlled trial of both the effectiveness and cost-effectiveness of the treatment of hypertrophic burn scars with Pulsed Dye Laser and standard care compared to standard care alone	09/07/2021	24/08/2021	21/05/2021	18/11/2021	04/01/2022	04/01/2022	20/01/2022	Both	Delays were caused between sponsor and Nuth resolving contracting queries
109	20/LO/0947	261727	A multicenter, non-randomized, open-label phase 1b study to determine the maximum tolerated and recommended phase 2 dose of the ATR Inhibitor BAY 1895344 in combination with pembrolizumab and to characterize its safety, tolerability, pharmacokinetics and preliminary anti-tumour activity in patients with advanced solid tumours	06/08/2021	07/12/2021	30/09/2020	20/01/2022	20/01/2022	21/01/2022	07/03/2022	NHS Provider	Delays were caused due to NHS approval from R&D. No eligible patient was identified by the research team until March 2022
110	21/LO/0517	299456	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial to Evaluate the Efficacy and Safety of Three Dose Levels of KVD824, an Oral Plasma Kallikrein Inhibitor, for Long-Term Prophylactic Treatment of Hereditary Angioedema Type I or II	31/08/2021	10/12/2021	21/09/2021	13/01/2022	17/01/2022	17/01/2022		Sponsor	The research site had supply problems, sponsor sent two lots of lab kits with an early expiry date and in date lab kits were only recently received late March 2022
111	21/NW/0140	291937	Clinical Evaluation of the StablePoint Catheter and Force-Sensing System for Paroxysmal Atrial Fibrillation.	02/11/2021	17/12/2021	22/06/2021	17/01/2022	24/01/2022	24/01/2022	15/03/2022	Neither	Patient sought but no eligible patients were identified until March 2022
112	20/LO/0423	269678	Is there a genotype-phenotype correlation in SDHB that can guide surveillance screening?	03/12/2021	06/01/2022	03/09/2020	11/01/2022	11/01/2022	11/01/2022	17/01/2022	Please select	
113	19/LO/0571	256756	Asthma Exacerbation Profile in patients on open label treatment with Benralizumab for severe eosinophilic asthma - an exploratory cohort study	04/12/2019	14/01/2022	22/01/2020	28/01/2022	16/02/2022	16/02/2022		Neither	Patients sought but no eligible patients have been identified
114	19/NW/0700	268843	A phase III trial of intensity-modulated proton beam therapy versus intensity modulated radiotherapy for multi-toxicity reduction in oropharyngeal cancer	16/09/2020	14/02/2022	12/12/2019	16/02/2022	18/02/2022	22/02/2022		Please select	
115	21/YH/0224	293189	Breastmilk fortification in preterm infants: a randomised controlled trial of two nutritionally equivalent fortifiers (PUFFIN - preterm milk fortification in neonates)	31/03/2021	03/12/2021	22/10/2021	04/02/2022	04/02/2022	04/02/2022		NHS Provider	Contracting Delays caused from the Trust due to collaboration agreement. No eligible patients have been identified due to strict eligibility criteria

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
116	20/EM/0245	284115	A Phase 3 Randomized, Double-blind, Multicenter, Global Study of Monalizumab or Placebo in Combination With Cetuximab in Patients With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck Previously Treated With an Immune Checkpoint Inhibitor. INTERLINK-1	09/07/2021	17/02/2022	18/12/2020	23/02/2022	28/02/2022	28/02/2022		Please select	
117	21/LO/0080	293186	A randomised open label trial to assess change in respiratory function for people with cystic fibrosis (pwCF) established on triple combination therapy (Kaftrio™) after rationalisation of nebulised mucoactive therapies (the CF STORM trial)	08/07/2021	18/11/2021	10/03/2021	16/12/2021	09/02/2022	10/02/2022		Sponsor	Contract signing delays were caused by sponsor with signature process. No eligible patients have been seen during the reporting period
118	21/EM/0062	293080	A 52-week, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority study assessing exacerbation rate, additional measures of asthma control and safety in adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with GSK3511294 compared with mepolizumab or benralizumab	20/07/2021	10/02/2022	20/04/2021	14/02/2022	14/02/2022	17/02/2022		Please select	
119	21/WA/0237	1003718	A randomized, parallel-group, double-blind, placebo-controlled, multicenter Phase III trial to investigate the efficacy and safety of secukinumab 300 mg administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with giant cell arteritis (GCA)	06/08/2021	27/01/2022	24/08/2021	09/02/2022	11/02/2022	16/02/2022	24/03/2022	Please select	
120	21/FT/0072	298360	A Phase III, Double-Blind, Randomized, Placebo-Controlled and Parallel-Group Study to Evaluate the Efficacy and Safety of Opicapone, as Add-on to Stable Levodopa (L-DOPA) Plus a Dopa Decarboxylase Inhibitor (DDCI) Therapy in Early Idiopathic Parkinson's Disease Patients, with an Open-Label Extension The EPSILON Study: Early ParkinSon with L-DOPA/DDCI and Opicapone	12/08/2021	26/01/2022	21/05/2021	17/02/2022	17/02/2022	18/02/2022		Please select	

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
121	21/LO/0467	300194	A dose confirmation study of FLT180a (adeno-associated viral vector containing the Padua variant of a codon-optimized human Factor IX gene) in adult subjects with hemophilia B.	23/08/2021	01/02/2022	19/08/2021	07/02/2022	18/02/2022	18/02/2022		Please select	
122	20/LO/0840	264482	Functional and Ultrasound guided Resection of Glioblastoma. A two stage trial. Stage 1 – Non-randomised collaborative learning and evaluation phase of participating centres (IDEAL Stage 2b study), followed by Stage 2 – A Multicentre Phase III trial with 2 mechanistic substudies.	02/11/2021	06/01/2022	05/10/2020	25/01/2022	14/02/2022	16/02/2022		Neither	No eligible patients seen during the reporting period
123	21/ES/0065	293383	Piloting an intervention using single case design to reduce uncertainty distress in those with long term health conditions.	08/11/2021	13/01/2022	27/07/2021	18/01/2022	16/02/2022	17/02/2022		Please select	
124	21/EE/0120	294986	A PHASE IIIb, GLOBAL, MULTICENTER, RANDOMIZED, VISUAL ASSESSOR-MASKED STUDY OF THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF A 36-WEEK REFILL REGIMEN FOR THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (VELODROME)	15/11/2021	01/02/2022	27/01/2022	02/02/2022	09/02/2022	11/02/2022	04/03/2022	Please select	
125	21/YH/0066	280583	Exploring the utility and acceptability of Faecal Immunochemical Testing (FIT) as a novel intervention for the improvement of Colorectal Cancer (CRC) surveillance in individuals with Lynch Syndrome.	17/01/2022	07/02/2022	18/05/2021	07/02/2022	16/02/2022	16/02/2022		Please select	
126	20/LO/1194	1003433	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of Brensocatib Administered Once Daily for 52 Weeks in Subjects with Non-Cystic Fibrosis Bronchiectasis – The ASPEN Study	03/03/2021	01/03/2022	26/02/2021	14/03/2022	16/03/2022	17/03/2022		Please select	
127	21/FT/0112	296487	A multi-center, double-blind, randomised, placebo-controlled, phase IIa trial to evaluate spesolimab (BI 655130) efficacy in patients with fibrostenotic Crohn's Disease	23/03/2021	24/02/2022	11/10/2021	04/03/2022	14/03/2022	14/03/2022		Please select	

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
128	19/LO/0461	250715	A prospective randomised multi-centre Trial comparing cArDiac MRI guided CRT versus Conventional CRT implantation in patients with Ischaemic Cardiomyopathy - TACTIC CRT	14/04/2021	17/01/2022	04/07/2019	19/01/2022	02/03/2022	02/03/2022		Sponsor	Delays were caused by the sponsor signing the contract
129	21/LO/0108	290969	A Phase 1b/2 Open Label Umbrella Study of Sasanlimab Combined with Anti-Cancer Therapies Targeting Multiple Molecular Mechanisms in Participants with Non-Small Cell Lung Cancer (NSCLC)	19/04/2021	04/03/2022	13/04/2021	16/03/2022	16/03/2022	18/03/2022		Please select	
130	21/FT/0099	1003997	A Phase IIB, Randomized, Double-blinded, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of MEDI6570 in Participants with a Prior Myocardial Infarction, Persistent Inflammation, and Elevated N-terminal Prohormone Brain Natriuretic Peptide	02/07/2021	08/03/2022	28/09/2021	18/03/2022	21/03/2022	22/03/2022		Please select	
131	21/WA/0219	298975	A two-part, randomized, placebo controlled, double blind, multicenter, Phase 3 study to evaluate the efficacy and safety of linerixibat for the treatment of cholestatic pruritus in participants with primary biliary cholangitis (PBC).	31/08/2021	16/02/2022	01/11/2021	21/02/2022	29/03/2022	29/03/2022		Sponsor	Delays were caused by the contracting delays with the sponsor company
132	21/SC/0297	283200	Utilisation of normothermic machine preservation in extended criteria livers - a national threshold-crossing study	20/09/2021	15/02/2022	10/11/2021	14/03/2022	18/03/2022	18/03/2022		Please select	
133	20/NS/0140	290159	ROWTATE: Multicentre Research Programme to Enhance Return to Work after Trauma - Work Package 3 and 4.	29/09/2021	16/03/2022	13/01/2021	24/03/2022	29/03/2022	30/03/2022		Please select	
134	21/LO/0287	290599	Controlled trial of High-risk coronary Intervention with Percutaneous left ventricular unloading	28/10/2021	09/02/2022	12/05/2021	10/02/2022	01/03/2022	01/03/2022		Please select	
135	20/EE/0254	283893	An Open-Label, Multicenter, Randomized Phase 3 Study of First-Line Encorafenib Plus Cetuximab with or without Chemotherapy Versus Standard of Care Therapy with a Safety Lead-In of Encorafenib and Cetuximab Plus Chemotherapy in Participants with Metastatic BRAF V600E-Mutant Colorectal Cancer	03/11/2021	28/02/2022	20/01/2021	03/03/2022	11/03/2022	11/03/2022		Please select	

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
136	20/SC/0423	288506	Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care.	21/12/2021	24/02/2022	02/03/2021	26/02/2022	17/03/2022	17/03/2022		Please select	
137	21/WS/0007	292519	AcQBlate Force Sensing Ablation System EU Study for Atrial Flutter	24/01/2022	21/02/2022	11/03/2021	22/02/2022	01/03/2022	02/03/2022		Please select	
138	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	12/04/2021	09/12/2021	28/06/2021	29/12/2021	04/01/2022	04/01/2022		Neither	No eligible patients seen during the reporting period
139	21/ES/0016	1003518	A double-blind, placebo-controlled, randomized, 18 month Phase 2a study to evaluate the efficacy, safety, tolerability and pharmacokinetics of oral UCB0599 in study participants with early Parkinson's Disease	17/11/2021	17/11/2021	21/04/2021	02/12/2021	17/01/2022	17/01/2022		Sponsor	Initial delays were caused by contracting delays with the sponsor company. Patients sought but no eligible patients identified
140	21/FT/0049	294544	A randomised double-blind placebo-controlled clinical trial investigating the effect and safety of oral semaglutide in subjects with early Alzheimer's disease (EVOKE)	06/05/2021	12/11/2021	20/05/2021	04/01/2022	06/01/2022	06/01/2022		Sponsor	Initial delays were caused by the sponsor delays with the drug. No eligible patients have been identified during the reporting period
141	21/NW/0112	291022	ASSURE: An Open Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects with Primary Biliary Cholangitis (PBC)	01/06/2021	16/11/2021	27/07/2021	08/12/2022	19/01/2022	19/01/2022		Sponsor	Delays were caused with contracting within the sponsor company. No eligible patient has been seen due to the strict eligibility criteria
142	21/NS/0038	291133	Bracing Adolescent Idiopathic Scoliosis (BASIS) Study – night-time versus full-time bracing in adolescent idiopathic scoliosis	07/07/2021	01/12/2021	08/04/2021	04/01/2022	10/01/2022	10/01/2022		Neither	The Spinal team are actively screening for patients eligible for the BASIS study. There have been no patients who meet the eligibility criteria
143	21/SW/0008	292203	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 1b/2a Study of WVE-003 Administered Intrathecally in Patients With Huntington's Disease	13/07/2021	11/01/2022	01/04/2021	24/01/2022	30/01/2022	31/01/2022		Neither	No patients have presented at clinic who would be suitable for the trial
144	21/NW/0276	300883	Development and feasibility testing of a multi-faceted theory-informed behavioural intervention targeting physical activity in adults with heart failure (InAct-HF)	18/11/2021	10/12/2021	22/10/2021	20/01/2022	14/01/2022	14/01/2022		Neither	Study has been slow to start because of research staff sickness due to COVID