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1	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	17/05/2021	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
2	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	07/04/2021	Sponsor	The remote SIV did not happen until 3rd March 2021. The study opened to recruitment on 22nd March and the team then actively looked for recruits
3	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	
4	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	21/06/2021	Sponsor	Delayed by sponsor because of freezer and used IMP vials and their storage. No patient consented until June 2021
5	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	17/05/2021	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.
6	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	15/04/2021	Neither	This study was only available to participants who had taken part in a previous study. Delays to recruitment were caused to their availability, medical staff availability and getting all in house documents/approvals in place
7	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		Sponsor	The trial received green light from pharmacy on the 5th Feb and on the 30th March the team were told all screening slots had been filled and the study had moved to waiting list. Since then the team have been waiting on a new protocol amendment which adds 75 patient slots

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8	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	44433	Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population
9	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	21/04/2021	Neither	No eligible patients were identified
10	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	44277	Please select	
11	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		NHS Provider	Recruitment has been delayed due to pharmacy green light only been given for this study on the 16th July, 2021. Participants have been contacted and screenings is being planned
12	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	12/07/2021	Sponsor	This study deals with very rare Patients and the treatment cohort is paused pending a decision by the dose review. The team have not been able to screen however, they expect to open for recruitment soon and the team have been waiting to see a patient from Dublin
13	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	16/07/2021	Neither	One eligible patient was approached who declined trial entry. The team did not find another eligible patient until July 2021
14	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		Neither	This study is looking for a very niche group of patients which was highlighted to the sponsor throughout set-up. Although, the team were confident they would recruit the study closed nationally before they were able to identify a patient

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15	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	44398	Sponsor	Following confirmation of C&C the sponsor notified Newcastle of an amendment which had to be locally approved before they would issue green light. The team weren't able to proceed with study activation based on the approved version of the protocol that was in place when C&C was granted. The amendment was approved on 2nd June, and the team received sponsor green light on 8th June
16	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	07/05/2021	Sponsor	Contracting delays with sponsor company caused initial delays and no patient was seen who fitted the eligibility criteria
17	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	15/06/2021	Neither	No suitable patients were identified until June due the strict eligibility criteria
18	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		NHS Provider	The study cannot recruit until 10 patients (not participants) have received the device. As they are not part of the study and will be used as practice for the PI/Sub I's we are waiting for the PI to create an information sheet for these people before the team can start the study
19	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	11/05/2021	Neither	No eligible patients were identified
20	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	44298	Sponsor	Contracting delays with sponsor company. The study opened on 17th March 2021 and recruited their first patient 26 days later.
21	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	28/04/2021	Please select	
22	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	44477	Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population
23	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	03/06/2021	Neither	Patients sought but no eligible patients identified

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24	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	27/04/2021	NHS Provider	Local Capacity and Capability review delays. Once this was resolved and the study opened the team sought eligible patients
25	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	14/04/2021	Please select	
26	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	44322	Please select	
27	19/WM/0364	257918	Letrozole or Clomifene, with or without metformin, for ovulation induction in women with polycystic ovary syndrome: a 2x2 factorial design randomised trial (The LOCI trial)	23/02/2021	23/02/2021	09/06/2020	14/04/2021	21/04/2021	21/04/2021	10/06/2021	Both	Delays intially were because of NHS Finance and sponsor answering finance queries. Other delays were caused by confirmation from sponsor for Green Light to recruit patients
28	20/LO/0181	275690	A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma	26/02/2021	22/03/2021	02/06/2020	26/04/2021	26/04/2021	26/04/2021	08/06/2021	Neither	No eligible patients were seen initially
29	19/LO/1381	257176	A Phase 4, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy and Safety of Erenumab in Adults With Chronic Migraine and Medication Overuse Headache	05/05/2020	14/01/2021	29/10/2019	20/04/2021	20/04/2021	21/04/2021	44358	Sponsor	Initial delays were caused by sponsor protocol amenedments. No eligible patient was seen until June 2021
30	20/NE/0264	286020	Post-Stroke rapid assessment of Cardiac arrhythmia evaluation- The Pace Study	23/02/2021	23/02/2021	10/02/2021	08/04/2021	08/04/2021	08/04/2021	21/04/2021	Both	Local capacity and capability reviews were not completed in time
31	20/LO/1021	283786	Randomised, double-blind, placebo-controlled, clinical study to evaluate the effect of opicapone 50 mg on Parkinson's disease patients with motor fluctuations and associated pain	16/11/2020	04/03/2021	16/10/2020	01/04/2021	08/04/2021	08/04/2021		NHS Provider	Due to Urgent public health studies that take priority at Newcastle the pharmacy team were unable to provide their greenlight until 30/06/2021. No patient has been identified who meets the eligibility criteria

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32	20/NE/0014	272055	Multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIG) and aspirin, versus IVIG and aspirin for prevention of coronary artery aneurysms in Kawasaki disease (KD-CAAP: Kawasaki Disease Coronary Artery Aneurysm Prevention trial)	16/11/2020	26/02/2021	18/02/2020	30/04/2021	30/04/2021	30/04/2021		Both	Contracting delays between both parties meant the study was not granted approval in time. The KD-CAAP study has not yet been given the Green Light by sponsor. This study is researching a rare condition in the paediatric population.
33	20/SC/0433	282917	Wrist Injury Strengthening Exercise: a randomised multicentre feasibility study of resistance exercise versus usual care for optimising function after distal radius fracture in adults aged 50 years or over	24/02/2021	24/02/2021	05/01/2021	26/04/2021	26/04/2021	26/04/2021	44420	Sponsor	Initial delays were caused by sponsor querying the protocol amendments. The reason this study was late to recruit is due to mainly logistical issues. There have been changes to clinic times due to COVID-19 and we have not always had available staff to cover. There was initially no eligible patients presented
34	20/WA/0266	285192	Prospective observational cohort study: To assess the utility of bio-degradable bile duct stent in the drainage of bile duct.	01/03/2021	01/03/2021	26/10/2020	20/04/2021	22/04/2021	22/04/2021	03/08/2021	Sponsor	Initial delays were caused by sponsor querying the protocol amendments. Delays have also been caused because the indications for the use of the stents used in this study is limited. Identifying patients has been slow especially with COVID screening criteria for patients
35	20/SC/0334	287932	A Multicentre, Adaptive, Randomised, Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalised Patients with COVID-19 Short Title: Therapeutics for Inpatients with COVID-19 (TICO) INSIGHT Protocol Number: 014 / ACTIV-3	12/03/2021	12/03/2021	30/09/2020	07/04/2021	13/04/2021	13/04/2021	44322	Please select	
36	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	
37	19/NE/0145	254931	FaR-RMS: An overarching study for children and adults with Frontline and Relapsed RhabdoMyoSarcoma	15/05/2019	19/03/2021	22/07/2019	12/05/2021	17/05/2021	17/05/2021	44342	Both	Contracting delays with costs caused the study to be delayed with approval
38	19/LO/0288	235544	A Randomised Placebo-Controlled Trial of Escitalopram and Nortriptyline with Standard Psychological Care for Depression in Parkinson's Disease	16/09/2019	23/02/2021	13/11/2019	18/05/2021	20/05/2021	20/05/2021	24/06/2021	Both	Delays were caused by contracting problems around the data sharing agreement alongside the standard contract
39	20/EM/0003	269023	Multicentre, open-label, randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress.	08/01/2020	24/03/2021	14/02/2020	06/05/2021	07/05/2021	07/05/2021	06/08/2021	Both	Initial delays were caused by the local capacity and capability review not being completed in time. Subsequent delays have been caused by a clarification and change of routine practice was needed regards to the saturation limits in the study. The registered nurse and PI also needing to self isolate which has delayed in the recruitment of patients to the study

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40	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	44389	Please select	
41	20/SC/0335	286668	An open-label, randomized study to assess the relative bioavailability (BA) and bioequivalence (BE) of fixed-dose combination (FDC) formulations of niraparib plus abiraterone acetate (AA) compared to niraparib and AA co-administered as single agents in men with prostate cancer	21/07/2020	01/03/2021	17/11/2020	21/05/2021	21/05/2021	24/05/2021	19/07/2021	Sponsor	Delays were caused by contracting delays with sponsor. No patient was identified that meet the strict eligibility criteria until July 2021
42	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
43	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
44	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	
45	20/LO/0963	281310	Randomized, double-blind, phase 3 study of tucatinib or placebo in combination with ado-trastuzumab emtansine (T-DM1) for subjects with unresectable locally-advanced or metastatic HER2+ breast cancer (HER2CLIMB-02)	07/09/2020	02/02/2021	23/10/2020	20/05/2021	21/05/2021	21/05/2021		Sponsor	Delays caused by contracting issues with sponsor - when study was submitted the sponsor was Seattle Genetics, company changed company name to SeaGen which required additional vendor assessments and finance reviews and assurances to be put into place, causing delays. Delays to recruitment have been caused by staffing within in the Cancer Team
46	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
47	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

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48	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		Sponsor	This study is on hold pending a substantial protocol amendment and the Newcastle site does not yet have green light to proceed
49	21/LO/0056	1003503	Interventional, randomized, double-blind, parallel-group, placebo-controlled delayed-start study to evaluate the 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
50	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	44364	Please select	
51	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	
52	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	44371	Please select	
53	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	
54	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	
55	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	44411	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

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56	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)
57	19/LO/1690	240451	Visualizing and Measuring Facial Expressions of Children with Cleft Lip using 3D Surface Data obtained from Depth Sensors	23/03/2021	24/03/2021	14/11/2019	01/06/2021	09/06/2021	09/06/2021		Sponsor	Initial delays were caused by the sponsor querying items within the contract. No patient has been identified that meets the eligibility criteria
58	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
59	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	44454	NHS Provider	Recruitment was delayed due to staff issues due to COVID and long term sick
60	20/NW/0260	1003209	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study of AG-881 in Subjects With Residual or Recurrent Grade 2 Glioma With an IDH1 or IDH2 Mutation	20/01/2021	20/01/2021	17/07/2020	15/06/2021	21/06/2021	21/06/2021	15/09/2021	Sponsor	The sponsor changed halfway throught the contract which caused huge delays. The study was late receiving the Green Light which caused delays with recruitment
61	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
62	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
63	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	
64	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	
65	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		Neither	Low number of patients are presenting at the hospital who meet the strict eligibility criteria

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66	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	
67	20/NE/0248	270777	Obeticholic acid for the Amelioration of Cognitive Symptoms trial - 1	13/09/2019	08/03/2021	19/01/2021	31/03/2021	01/04/2021	01/04/2021	44371	Neither	Delays to recruitment was caused because the patient needed an MRI scan as per protocol, and was booked into the first one that came available
68	21/YH/0026	289207	The HistoSonics System for treatment of primary and metastatic livertumors using histotripsy.	44090	44340	44302	44340	44341	44356	44385	Please select	
69	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	44061	44357	44035	44357	44365	44365	30/06/2021	Please select	
70	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
71	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
72	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
73	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

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74	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
75	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.
76	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		Neither	The team have seen only 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.
77	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	44424	Please select	
78	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
79	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	44419	19/08/2021	19/08/2021	44455	Please select	
80	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
81	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	
82	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	44462	Please select	

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83	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
84	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	44428	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
85	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	44487	Please select	
86	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	
87	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
88	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	44413	Please select	
89	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 that usual
90	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 goverance 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

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91	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		Neither	A number of women have received the Patient Information Leaflet but were not prepared to commit to the time commitment of the study
92	19/WS/0123	227793	Motor Neurone Disease Systematic Multi-arm Adaptive Randomised Trial (MND-SMART)	10/02/2020	22/02/2021	14/10/2019	07/07/2021	20/09/2021	20/09/2021	25/10/2021	Both	This study was submitted to R&D in February 2021, shortly after an amendment was submitted that required an additional finance review, the contract was at signature stage when the Newcastle pharmacy team expressed capacity concerns and said they were unable to support the study at the time. Pharmacy reconfirmed capacity to support the study on Friday 17th September 2021 by email
93	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	44461	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
94	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	44488	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)
95	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		Sponsor	Sponsor delays were caused because they to a long time to sign the contract. No patient has been recruited because staff, resources and time have been diverted to COVID-19 studies over the last year. This is a critical care study
96	21/L0/0449	1003652	Randomised controlled trial of plasma cell depletion for severe Graves' disease	29/10/2020	25/08/2021	08/07/2021	44447	15/09/2021	15/09/2021	11/10/2021	Please select	
97	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		Neither	No eligible participants seen due to them taking second line drugs that excludes them from the trial. The team are actively searching for participants
98	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

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99	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	44460	Please select	
100	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		Neither	Patients have been sought and one patient who met the criteria declined. The team are trying very hard to recruit but are limited due to COVID related factors
101	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		Neither	Recruitment has been delayed due to participants who have expressed interest in the study being hesitant to travel long distances to site due to COVID
102	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	44448	Please select	
103	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	
104	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	
105	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
106	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	
107	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		Sponsor	Initial delays were caused by the sponsor giving the incorrect invoicing address on the contract. No eligible patient has been seen during the reporting period

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108	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		Sponsor	Delays were caused by sponsors response to financial queries. No patient has been seen who fits the eligibility criteria
109	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
110	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
111	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		Sponsor	Delays were caused waiting for the sponsor signature on the contract. No eligible particants seen during this reported period
112	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
113	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
114	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.
115	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	44511	Please select	
116	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		Sponsor	Green light from sponsor was not received until 17/12/21 because of delayed documentation

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117	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
118	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
119	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
120	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		Please select	
121	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	
122	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
123	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		Please select	
124	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		Please select	
125	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 bee identified during this reporting period
126	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		Please select	
127	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		Please select	
128	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

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129	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		Please select	
130	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	44522	Please select	
131	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	44529	Please select	
132	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		Please select	
133	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		Please select	
134	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		Please select	
135	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		Please select	
136	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		NHS Provider	Support departments approvals were out of date and had to be requested before the study was allocated for set up. No eligible patient seen during the reporting period
137	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 cardio-protective 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	44559	NHS Provider	Local capacity and capability review was not completed in time

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138	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
139	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		Please select	
140	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		Please select	
141	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		Please select	
142	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		Please select	
143	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		Please select	
144	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	
145	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		Sponsor	Delays were caused by sponsor changing the wording in the contract
146	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		Please select	