

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	17/EE/0078	223150	Evaluating the efficacy of PKU Synergy in patients expressing phenylketonuria or hyperphenylalaninemia	18/09/2017	05/10/2017	27/03/2017	05/10/2017	18/10/2017	23/10/2017	01/11/2017	Please select	
2	17/EM/0236	221138	Dose finding phase IIb study of Bavisant to evaluate its safety and efficacy in treatment of excessive daytime sleepiness (EDS) in Parkinson's Disease (PD).	13/11/2017	13/11/2017	05/08/2017	14/09/2017	22/11/2017	22/11/2017	16/04/2018	Both	Sponsor was awaiting pharmacy confirmation that all processes were in place before allowing the study to start recruiting patients
3	17/SC/0440	226052	In vivo human motor unit imaging	06/11/2017	23/11/2017	27/10/2017	24/11/2017	24/11/2017	24/11/2017	30/11/2017	Please select	
4	17/EE/0038	217456	A RANDOMIZED, DOUBLE-BLIND, PLACEBOCONTROLLED, MULTI-CENTER PHASE II STUDY TO EVALUATE THE SAFETY AND EFFICACY OF RO7123520 AS ADJUNCT TREATMENT IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS AND AN INADEQUATE RESPONSE TO TNF- α INHIBITORS	09/10/2017	23/10/2017	13/04/2017	25/10/2017	07/11/2017	08/11/2017		Sponsor	Sponsor had not planned SIV when study was given the green light. No eligible participants have been seen during the reported period because of the strict eligibility criteria due to the limited patient population and known high screen failure rate
5	17/LO/0633	220388	A PHASE I, PLACEBO CONTROLLED, DOUBLE-BLIND, DOSE ESCALATION CLINICAL TRIAL TO EVALUATE THE SAFETY AND IMMUNE RESPONSES OF IMCYSE's IMCY-0098 IN PATIENTS WITH RECENT ONSET TYPE 1 DIABETES.	09/10/2017	24/10/2017	28/04/2017	30/10/2017	20/11/2017	21/11/2017	22/03/2018	Neither	The Cohort for this study is newly diagnosed Type 1 Diabetes Patients. The Cohort needed to present at a Diabetes Centre as a newly diagnosed patient. Therefore the team were unable to actively search for patients
6	17/SC/0232	220550	PHASE 1B/PHASE 3 MULTICENTER STUDY OF AVELUMAB (MSB0010718C) IN COMBINATION REGIMENS THAT INCLUDE AN IMMUNE AGONIST, EPIGENETIC MODULATOR, CD20 ANTAGONIST AND/OR CONVENTIONAL CHEMOTHERAPY IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL)	06/11/2017	06/11/2017	06/07/2017	15/11/2017	21/11/2017	21/11/2017		Sponsor	Sponsor has suspended site/study while they evaluate the first 6 and/or 12 DLT evaluable patients in each treatment arm after the last patient has completed one cycle (4 weeks) of treatment. Enrollment will be halted during this period while the first 6 DLT evaluable patients in each treatment arm are evaluated for safety.
7	16/LO/2008	208047	A Single Arm, Open-Label, Multi-Centre, Phase I/II Study Evaluating the Safety and Clinical Activity of AUTO2, a CAR T Cell Treatment Targeting BCMA and TACI, in Patients with Relapsed or Refractory Multiple Myeloma.	13/11/2017	16/11/2017	31/03/2017	20/11/2017	29/11/2017	30/11/2017	26/03/2018	Neither	The inclusion/exclusion criteria for this study is very exact, a number of patients were approached and proved unsuitable. This is due to the highly complex nature of the study treatment and the expected side-effects after the re-infusion of the modified T-cells
8	17/LO/1018	224051	An Open-Label, Multi-Centre, Safety Study of Fixed-Dose Durvalumab + Tremelimumab Combination Therapy or Durvalumab Monotherapy in Advanced Solid Malignancies	30/10/2017	16/11/2017	13/09/2017	14/11/2017	22/11/2017	23/11/2017	19/04/2018	Neither	This study is looking for specific patients who don't often present at clinic. No eligible patient was seen in the first 70 days. However, patient information sheets have been given out to 4 patients and the team is hopeful of recruiting their first patient
9	17/NE/0270	231054	Serum sample collection to determine analytical performance characteristics of the ADVIA CENTAUR® Free Beta Human Chorionic Gonadotropin assay	02/10/2017	02/10/2017	26/09/2017	18/10/2017	08/11/2017	08/11/2017	16/11/2017	Please select	

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10	17/EE/0297	225586	A SINGLE-ARM, MULTICENTER PHASE IIIB CLINICAL TRIAL TO EVALUATE THE SAFETY AND TOLERABILITY OF PROPHYLACTIC EMICIZUMAB IN HEMOPHILIA A PATIENTS WITH INHIBITORS	13/11/2017	13/11/2017	06/09/2017	15/11/2017	23/11/2017	23/11/2017	18/12/2017	Please select	
11	17/LO/1147	222154	Tralokinumab monotherapy for moderate-to-severe atopic dermatitis ECZTRA 2 (ECZema TRAlokinumab trial no. 2)	25/09/2017	24/10/2017	10/08/2017	17/10/2017	07/11/2017	09/11/2017	21/12/2017	Please select	
12	16/LO/2126	218039	A randomized trial comparing the ELLUVIA™ drug-eluting stent versus bare Metal self-expanding nitinol stents in the treatment of superficial femoral and/or proximal popliteal arteries	06/11/2017	06/11/2017	24/02/2017	14/11/2017	23/11/2017	23/11/2017	09/01/2018	Please select	
13	16/LO/0708	200170	A Phase I Study Evaluating TAS-116 in Patients With Advanced Solid Tumors	20/11/2017	12/12/2017	30/06/2016	07/12/2017	15/12/2017	20/12/2017	15/01/2018	Please select	
14	16/SC/0376	202786	Testing Radical prostatectomy in men with prostate cancer and oligometastases to the bone: a randomised controlled feasibility trial	02/10/2017	14/11/2017	10/10/2016	27/11/2017	01/12/2017	04/12/2017	24/01/2018	Neither	Patients eligible for this study are not frequently found. The study was lucky to have consented 1 patient in two months. They had screened several patients before the 70 day target but all were ineligible or refused to take part in the study
15	17/NE/0173	218482	Randomised, double-blind, placebo-controlled, parallel-group, multi-centre, phase III trial to investigate the efficacy, safety and tolerability of Naloxone HCl PR Tablets in patients with opioid induced constipation	21/08/2017	15/11/2017	11/08/2017	20/11/2017	01/12/2017	06/12/2017		Both	The team did not receive the green light from pharmacy until 18/04/2018 due to the IMP being sent to the wrong site and a outstanding GCP certificate for PI
16	17/NE/0259	223665	Can a holistic model of rehabilitation improve quality of life after treatment for lower extremity sarcoma? A pilot and feasibility study.	28/11/2017	28/11/2017	25/10/2017	05/12/2017	05/12/2017	05/12/2017	12/01/2018	Please select	
17	17/EM/0327	230578	RCT and meta-analysis testing effectiveness and cost-effectiveness of a tailored text message programme (MiQuit) for smoking cessation in pregnancy	13/11/2017	13/11/2017	06/11/2017	06/12/2017	15/12/2017	15/12/2017	15/01/2018	Please select	
18	17/NS/0018	223787	Female Urgency, Trial of Urodynamics as Routine Evaluation (FUTURE study); a superiority randomised clinical trial to evaluate the effectiveness and cost effectiveness of invasive urodynamic investigations in management of women with refractory overactive bladder symptoms	15/11/2017	15/11/2017	11/08/2017	04/12/2017	05/12/2017	05/12/2017	30/01/2018	Neither	No eligible patients was seen who fitted the eligibility criteria during this period
19	17/EM/0301	209448	Sedation AND Weaning In Children: the SANDWICH trial	15/12/2017	15/12/2017	29/09/2017	15/12/2017	15/12/2017	15/12/2017	06/02/2018	Please select	

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20	17/NE/0165	217768	AN OPEN-LABEL, SINGLE-ARM STUDY TO EVALUATE THE EFFECTIVENESS AND SAFETY OF OCRELIZUMAB IN PATIENTS WITH EARLY STAGE RELAPSING REMITTING MULTIPLE SCLEROSIS	23/10/2017	23/10/2017	07/09/2017	28/11/2017	06/12/2017	06/12/2017	08/01/2018	Sponsor	Initial delays were caused by the sponsor not signing the contract in time. Delays were further impacted by the studies strict inclusion criteria and the teams inability to find suitable patients
21	16/ES/0110	207747	Treatment of Osteogenesis Imperfecta with Parathyroid hormone and Zoledronic acid	18/09/2017	14/11/2017	12/01/2017	23/11/2017	01/12/2017	04/12/2017	22/06/2018	Sponsor	The study missed the 70 day benchmark because the Sponsor's authorisation to open the Clinical Trial at our site was received 11 days from this deadline. Participants were sought but only two eligible participants were identified. However they declined participation in the trial
22	16/LO/1318	187932	Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBsAg clearance. (NUC-B)	16/10/2017	16/10/2017	21/09/2016	01/12/2017	07/12/2017	07/12/2017	13/02/2018	Sponsor	Study did not recruit within the 70 day window due to delays with sponsor in opening the study to recruitment at site. Study Received R&D Capacity and Capability on 07/12/2017 and Sponsor did not grant Green light until 19/01/2018
23	17/NE/0124	216591	A randomised, double-blind, controlled, parallel-group, multi-country study to investigate the effect of a partially hydrolysed infant formula with added synbiotics on gut microbiota composition and clinical effectiveness in infants at high risk of developing allergy.	03/10/2017	03/10/2017	10/07/2017	11/10/2017	20/10/2017	20/10/2017	06/12/2017	Please select	
24	16/SS/0137	199347	Alteplase-Tenecteplase Trial Evaluation for Stroke Thrombolysis (ATTEST 2)	12/10/2017	12/10/2017	11/01/2017	24/11/2017	04/12/2017	04/12/2017	13/01/2018	Sponsor	Initial delays were caused by the sponsor querying aspects of the contract. There were also delays receiving PIN numbers and Usernames as training not completed by all members of the team. Also drugs not released to pharmacy until all members of the team had completed drug administration training. No patient was found in the remaining days who fitted the study criteria
25	17/NE/0148	226163	Open-Label, Multicenter, Phase I Dose Escalation Study of MEN1309, a CD205 Antibody-Drug Conjugate, in Patients with CD205-Positive Metastatic Solid Tumors and Non-Hodgkin Lymphoma	09/10/2017	16/10/2017	05/07/2017	27/09/2017	25/10/2017	25/10/2017		Sponsor	The study was given the green light by the Trust on 25 Oct, which was before we had a SIV, however there were issues from the sponsor and these are still on going so have not received the green light from sponsor. The SIV which was due to take place in November was postponed due to the CRA being unwell. The SIV took place on Thursday 21 December but there have been ongoing issues with the lab kits and having the antibodies available to stain the reference slides
26	17/LO/0108	221119	MANagement of high bleeding risk patients post bioresorbable polymer coated STent implantation with an abbreviated versus prolonged DAPT regimen – MASTER DAPT	16/10/2017	16/10/2017	10/04/2017	23/10/2017	09/11/2017	09/11/2017	26/01/2018	Neither	The study missed the 70 day benchmark as the issue was with a difficult population of patients to find, they need to be at a high risk of bleeding and treated with a particular stent before they are eligible to participate in the study
27	17/NE/0297	227451	Is it possible to develop a complex intervention to improve the outcome of falls in people with dementia (Work package 4)?	22/01/2018	22/01/2018	08/11/2017	23/01/2018	23/01/2018	23/01/2018	27/02/2018	Please select	

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28	17/NE/0367	237110	A 24-month Phase II Open-label, Multicenter Long-term Extension Study to Assess the Long-term Safety and Efficacy of Vamorolone in Boys with Duchenne Muscular Dystrophy (DMD)	11/12/2017	15/01/2018	12/01/2018	16/01/2018	16/01/2018	16/01/2018	22/01/2018	Please select	
29	16/LO/1653	211863	SAFETY AND PHARMACOKINETICS OF ODM-207 IN PATIENTS WITH SELECTED ADVANCED SOLID TUMOURS: AN OPEN-LABEL, NON-RANDOMISED, UNCONTROLLED, MULTICENTRE, FIRST-IN-HUMAN STUDY WITH COHORT EXPANSION	20/11/2017	20/11/2017	17/12/2016	19/12/2017	03/01/2018	04/01/2018	23/02/2018	Sponsor	Original delays were caused due to the equipment agreement needing to be in place. It is an early phase study that is slot driven, so we need an open slot and an eligible patient to appear at the same time and no participant was seen during the reporting period
30	17/EE/0177	220722	A Phase 3 Randomized, Controlled, Open-Label Study of Selinexor, Bortezomib, and Dexamethasone (SVD) Versus Bortezomib and Dexamethasone (VD) in Patients with Relapsed or Refractory Multiple Myeloma (RRMM)	18/12/2017	18/12/2017	24/07/2017	21/12/2017	04/01/2018	04/01/2018	27/03/2018	Neither	As with many of the Malignant Haematology Cancer, this is classed as a rare disease which combined with no suitable patients being identified across the geographic catchment area has led to this study missing the 70 day recruitment target
31	17/YH/0181	227102	Phase 2 Study of TAK-659 in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma After at Least 2 Prior Lines of Chemotherapy	11/12/2017	11/12/2017	25/07/2017	20/12/2017	04/01/2018	04/01/2018	26/02/2018	Neither	This is a rare disease study and the exacting inclusion criteria, whereby suitable subjects must have had at least 2 prior lines of therapy has caused the 70 day recruitment target to be exceeded.
32	17/EE/0255	227279	A DOUBLE-BLIND, RANDOMISED, PLACEBO CONTROLLED STUDY OF THE EFFICACY AND SAFETY OF THREE DOSES OF ORVEPITANT IN PATIENTS WITH CHRONIC REFRACTORY COUGH	13/11/2017	13/11/2017	26/07/2017	21/12/2017	04/01/2018	05/01/2018	06/03/2018	Sponsor	Initially the sponsor took longer than expected with the contract sign off and authorisation. This left 18 days to recruit the patient however, and an extensive green light procedure has to be undergone before the team are given permission to commence recruitment. There were also difficulties at the time of greenlight in identifying suitable patients (most patients didn't qualify because of timelines set out in the exclusion criteria)
33	17/WM/0239	223251	Ankle Injury Rehabilitation - A multi-centre randomised controlled trial to assess the difference between plaster cast and functional bracing in the management of ankle fractures.	17/11/2017	17/11/2017	04/07/2017	01/12/2017	11/01/2018	26/01/2018	07/02/2018	Sponsor	Delays with signatures from sponsor caused the study to miss the 40 day deadline. Contracting delays which caused delayed confirmation of capacity and capability also resulted in the study missing the 70 day target as it delayed SIV and recruitment start date
34	17/LO/0962	220190	Helping Pregnant smokers to quit: A multi-centre RCT of electronic cigarettes vs. nicotine patches (usual care)	18/12/2017	15/01/2018	24/07/2017	19/01/2018	31/01/2018	05/02/2018	22/02/2018	Please select	
35	17/NE/0238	225047	A Phase 1b, Open-label, Single-dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of MK-7655A in Pediatric Subjects From Birth to Less Than 18 Years of Age With Confirmed or Suspected Gram-negative Infections	12/02/2018	12/02/2018	11/07/2017	16/02/2018	27/02/2018	27/02/2018		Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria meaning patients already on a clinical trial where IMP is administered are excluded
36	17/NE/0027	215796	CReST 2 - Colorectal Endoscopic Stenting Trial 2	23/11/2017	23/11/2017	03/04/2017	02/02/2018	23/02/2018	23/02/2018	27/06/2018	NHS Provider	The new interventions committee took longer than expected to get back with comments causing the contract to be signed and approved late causing the study to miss the 70 day benchmark

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37	17/NE/0308	226369	Effects of a 6-month practical resistance training programme on muscle function and bone mineral density in adults with inactive or mildly active Crohn's disease: Study protocol for a randomised controlled trial	22/01/2018	25/01/2018	17/11/2017	06/02/2018	06/02/2018	06/02/2018	26/03/2018	Please select	
38	17/EM/0183	220783	A randomised, double-blind, parallel group PhIII study to assess the clinical efficacy and safety of 100 mg SC Mepolizumab as an add on to maintenance treatment in adults with severe bilateral nasal polyps	12/02/2018	12/02/2018	28/06/2017	16/02/2018	28/02/2018	28/02/2018	15/06/2018	Neither	No eligible patients seen due to the strict criteria
39	17/EM/0324	225749	A phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate efficacy and safety of octreotide capsules in patients who previously tolerated and demonstrated biochemical control on injectable somatostatin receptor ligands (SRL) treatment	20/02/2018	20/02/2018	30/10/2017	06/03/2018	19/03/2018	19/03/2018		Neither	This study has a particularly complex inclusion criteria and the final inclusion sits with the sponsor. The team have identified one participant and if sponsor gives the OK screening will go ahead
40	17/WM/0248	213348	Preventing cardiac damage in patients treated for breast cancer: a phase 3 Randomised, Open label, blinded endpoint, trial of enalapril to prevent Anthracycline-induced CardioToxicity (PROACT).	22/01/2018	07/02/2018	09/08/2017	15/02/2018	26/02/2018	05/03/2018	14/05/2018	Neither	Patients are now being Oncotype Tested (Genomic test) which is changing treatment plans. The team are finding that not as many patients are having FEC chemotherapy alone to make them eligible. The team has looked at all the patients starting FEC since the trial opened and only one patient was eligible for the trial. This patient has now been recruited
41	17/SC/0164	210735	CRYOSTAT-2: A multi-centre, randomised, controlled trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring major haemorrhage protocol (MHP) activation	29/01/2018	08/02/2018	26/05/2017	23/02/2018	09/03/2018	13/03/2018	01/05/2018	Neither	No eligible patients admitted was recruited within the time frame. The patient group are admitted in emergency situations which are sporadic and rare in their occurrence
42	17/WM/0308	226910	Randomized, Double-Blind, Phase 3B Trial to Evaluate the Safety and Efficacy of 2 Treatment Regimens of Aztreonam 75 mg Powder and Solvent for Nebulizer Solution / Aztreonam for Inhalation Solution (AZLI) in Pediatric Subjects with Cystic Fibrosis (CF) and New Onset Respiratory Tract Pseudomonas aeruginosa (PA) Infection/Colonization	25/01/2018	25/01/2018	10/09/2017	21/02/2018	13/03/2018	13/03/2018		Sponsor	Delays were caused because of the sponsor rejecting the travel clause the Trust wanted inserted into the contract. Which meant the contract had to go back and forward between the sponsor and finance to resolve. No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population
43	17/NW/0022	219189	Post-Authorization Safety, Tolerability and Immunogenicity Evaluation of HyQvia in Pediatric Subjects with Primary Immunodeficiency Diseases	18/09/2017	12/10/2017	06/03/2017	02/02/2018	02/02/2018	22/02/2018		Sponsor	It took the sponsor 3 months to sent the contract to Newcastle partially signed. The contract was back and forward to sponsor causing numerous delays to approve the study which meant the study missed the benchmark. No patient has been identified to date

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44	17/EM/0315	220334	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease	15/01/2018	15/01/2018	03/11/2017	17/01/2018	29/01/2018	29/01/2018		Sponsor	There have been issues providing the phantom CT scan transmission to the sponsor, which is why the sponsor has not been able to activate the site yet. The team are working with the sponsor to address the problem
45	17/NW/0247	222303	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Genicriviroc in Adult Subjects with Nonalcoholic Steatohepatitis and Liver Fibrosis	19/12/2017	19/12/2017	30/08/2017	12/01/2018	29/01/2018	29/01/2018		Sponsor	Initial delays were due to the Xmas and sponsor not getting the contract back on time. This was further impacted due to issues discovered at the SIV with the sponsors IT systems that was used for drug dispensing. The system did not allow pharmacy to create unscheduled visits or allocate a reserve kit for patients. This could have created safety issues as pharmacy have to ensure that participants at all times receive adequate amounts of the IMP between visits should there be an unforeseen issue. This issues was resolved and pharmacy gave the greenlight and the team were able to activate on 19.03.18
46	17/SC/0242	222650	A Phase 2A, Randomized, Double-Blind, Placebo- Controlled, Multi-Center Study of Intravenous FDY-5301 in Acute Myocardial Infarction	11/09/2017	05/10/2017	12/09/2017	06/10/2017	18/10/2017	23/10/2017	24/01/2018	Neither	The study did not recruit in the first 70 days due to the type of Myocardial Infarction (MI) presentation and the time constraints of the (Magnetic Resonance Imaging) MRI procedure
47	17/NE/0092	220929	A phase 3 C Difficile vaccine efficacy study - PF-06425090 for prevention of Clostridium difficile infection (CDI)	31/10/2017	31/10/2017	05/07/2017	06/11/2017	21/11/2017	21/11/2017	01/05/2018	Sponsor	The sponsor raised the age range for over 50's to over 60's which greatly reduced the potential population. No eligible participant has been seen during the reported period
48	18/LO/0115	239046	Acceptability and clinical trial feasibility evaluation of auditory rhythmical cueing to improve gait and physical activity in community dwelling stroke survivors	12/03/2018	12/03/2018	30/01/2018	14/03/2018	14/03/2018	14/03/2018	18/04/2018	Please select	
49	17/WM/0110	212527	Paediatric Hepatic International Tumour Trial	02/03/2018	02/03/2018	28/04/2017	16/03/2018	21/03/2018	21/03/2018	22/03/2018	Please select	
50	17/SW/0127	225959	A multicentre randomised trial of First Line treatment pathways for newly diagnosed Immune Thrombocytopenia: Standard steroid treatment versus combined steroid and mycophenolate.	12/02/2018	12/02/2018	03/07/2017	14/02/2018	01/03/2018	01/03/2018	16/03/2018	Please select	
51	17/NW/0193	216411	IntAct: Intraoperative Fluorescence Angiography to Prevent Anastomotic Leak in Rectal Cancer Surgery	07/02/2018	07/02/2018	20/04/2017	06/03/2018	12/03/2018	12/03/2018	29/05/2018	Sponsor	This study took 33 days to approve as there were delays receiving the contract from the sponsor. The study also did not gain green light from the Study Centre until the 12th March, 2018. No eligible patients were identified at the Multidisciplinary Team meeting until the first eligible patient was seen in May who entered the study
52	17/NE/0137	216108	A Phase 1b Study to Evaluate TAK-659 in Combination With Nivolumab in Patients With Advanced Solid Tumors	04/12/2017	23/01/2018	30/05/2018	06/02/2018	09/02/2018	12/02/2018	01/05/2018	Neither	This study deals with a rare disease and is a phase 1, slot driven study. The team had to wait for an eligible participant and an open slot to coincide for a patient to be recruited
53	17/SC/0391	227067	The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial	26/01/2018	26/01/2018	07/09/2017	02/02/2018	19/02/2018	19/02/2018	23/03/2018	Please select	

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54	17/WS/0137	228128	A Pivotal Randomized Study Assessing Vagus Nerve Stimulation (VNS) During Rehabilitation for Improved Upper Limb Motor Function After Stroke (VNS-REHAB)	24/01/2018	24/01/2018	27/09/2017	24/01/2018	05/02/2018	05/02/2018	10/04/2018	Neither	The eligibility criteria is very specific for this trial was difficult with lots of screening via physio assessments for patients to be identified. Patients then have to be assessed to establish if they are suitable for surgery and medication changed if needed prior to surgery. The team have to find a date for the surgeon and the team from America to come over for the surgery to take place
55	17/NE/0325	227986	EMPOWER: EMesis in Pregnancy - Ondansetron With mEtoplopramide.	11/12/2017	08/01/2018	30/11/2017	06/02/2018	06/02/2018	08/02/2018	10/07/2018	Sponsor	The study was late getting the green light from sponsor; Delays with the IMP manufacturing/packaging resulted in delays to the whole trial and issues with the eCRF
56	17/EE/0067	219960	The efficacy and safety of intra-arterial administration of Rexmyelocel-T to treat critical limb ischemia in subjects with diabetes mellitus: two pivotal, placebo-controlled, double-blind, parallel-group adaptive trials (Trial 2 - The efficacy and safety of intra-arterial administration of Rexmyelocel-T to treat ischemic ulcers in subjects with critical limb ischaemia Rutherford Category 5 and diabetes mellitus: a pivotal, placebo-controlled, double-blind, parallel-group adaptive trial).	27/03/2018	27/03/2018	29/06/2017	26/03/2018	04/04/2018	04/04/2018		Sponsor	The Site Initiation Visit (SIV) on the 02/05/2018 and the team were under the impression they could start recruiting soon after. However, on the same day the sponsor informed them not to start recruiting until they opened their Frankfurt Site, where the stem cells go for manipulation. The sponsor already had a site in Seville however, the team were told they could not use this any longer, due to the time and distance involved. The team/study are still awaiting for the Frankfurt Site to open
57	16/EE/0412	208292	The efficacy of intra-arterial administration of BM-MNCs to restore blood flow, treat ulcers, improve mobility and improve quality of life of diabetic patients with critical limb ischemia: A multicenter, randomized, double blind, and placebo-controlled trial	27/03/2018	27/03/2018	19/06/2017	26/03/2018	04/04/2018	04/04/2018		Sponsor	The Site Initiation Visit (SIV) on the 02/05/2018 and the team were under the impression they could start recruiting soon after. However, on the same day the sponsor informed them not to start recruiting until they opened their Frankfurt Site, where the stem cells go for manipulation. The sponsor already had a site in Seville however, the team were told they could not use this any longer, due to the time and distance involved. The team/study are still awaiting for the Frankfurt Site to open
58	17/NE/0240	224762	A Multi-Center, Prospective, Pragmatic, Randomized, Controlled Clinical Trial to Compare HF10 Therapy to Conventional Medical Management in the Treatment of Non-Surgical Refractory Back Pain	21/02/2018	21/02/2018	08/08/2017	28/03/2018	04/04/2018	04/04/2018	03/05/2018	Both	The study took 42 days to approve as there were delays receiving the contract from the sponsor. The delay in recruitment was due to the need to organise a Saturday Theatre list specifically for the patients in this study to optimise resources. The study identified 4 potential participants and the implants took place on a Saturday list but also an extra clinic was involved, to enable screening, consent and to proceed with the first visit
59	16/LO/1637	211258	First-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety of Axl-specific antibody-drug conjugate (HuMax®-AXL-ADC) in patients with solid tumors	12/04/2018	12/04/2018	08/11/2016	04/04/2018	20/04/2018	20/04/2018	12/06/2018	Neither	This study is a rare disease Phase 1, slot driven study. The team has to wait for an eligible participant to be available at the same time as an open slot

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60	17/YH/0269	228372	A Prospective, Open, Non-Comparative Multicentre Study to Evaluate a Fibrous Silver Dressing (DURAFIBER™ Ag) in the Treatment of Moderate to Highly Exuding Venous Leg Ulcers	07/03/2018	07/03/2018	25/02/2018	26/03/2018	09/04/2018	09/04/2018		Sponsor	The study took 30 days to approve as there were delays receiving the partially executed contract from the sponsor. Unfortunately, once the study was approved the sponsor did not issue green light 23/05/18. We were required to have a further SIV, which took time to arrange due to the sponsor initially not completing on the date arranged. The team have been actively looking for patients, but due to a staff shortage and only a couple of clinics per week, no patient has been found to date
61	17/LO/0334	214459	FLO-ELA: FLuid Optimisation in Emergency LAparotomy. Open, multi-centre, randomised controlled trial of cardiac output -guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery.	23/03/2018	23/03/2018	23/03/2017	05/04/2018	23/04/2018	23/04/2018	25/04/2018	Sponsor	There were queries regarding setup fees with the sponsor which caused delays
62	17/EE/0481	226412	Pre-Implantation Trial of Histopathology In renal Allografts (PITHIA)	15/03/2018	15/03/2018	05/01/2018	28/03/2018	09/04/2018	09/04/2018		Sponsor	Although the Newcastle site has Confirmation of Capacity (CoC) the National Trial will be unable to begin until all sites have CoC. Once this happens the study will require cluster randomisation prior to initiating recruitment
63	17/YH/0220	227317	Reducing perioperative risk in chronic obstructive pulmonary disease – A feasibility study	20/11/2017	13/03/2018	11/08/2017	19/03/2018	29/03/2018	04/04/2018	16/05/2018	Please select	
64	16/LO/0994	204296	A phase 1/2 dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of DTX-SPL8783 (a docetaxel (DTX)-dendrimer conjugate) as monotherapy in patients with advanced solid tumours or in combination with nintedanib in patients with non-small cell lung cancer (NSCLC)	15/02/2018	15/02/2018	10/08/2016	20/03/2018	04/04/2018	04/04/2018	17/04/2018	Sponsor	The study was delayed because of the financial vetting procedure
65	17/EE/0291	203703	A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma	19/02/2018	20/03/2018	31/07/2017	26/03/2018	29/03/2018	03/04/2018		Neither	This study was for a rare cancer and there had been a change in protocol that excluded patients who were suitable for auto or all stem cell transplant, which greatly reduced the potential recruitment population. The team took a decision to close the study at Newcastle
66	16/NS/0106	212541	Reducing Asthma Attacks in Children using Exhaled Nitric Oxide as a biomarker to inform treatment strategy - a randomised trial (RAACENO)	27/02/2018	27/02/2018	04/04/2017	02/03/2018	03/04/2018	03/04/2018	30/04/2018	NHS Provider	This study required the contract to be signed by the PI – there were delays receiving this from the Research Team
67	17/LO/0812	226255	A SINGLE-ARM, OPEN-LABEL, MULTI-CENTRE, PHASE I/II STUDY EVALUATING THE SAFETY AND CLINICAL ACTIVITY OF AUTO3, A CAR T CELL TREATMENT TARGETING CD19 AND CD22 FOLLOWED BY CONSOLIDATION WITH ANTI PD1 ANTIBODY IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B CELL LYMPHOMA	12/03/2018	12/03/2018	26/07/2017	16/03/2018	03/04/2018	03/04/2018	26/07/2018	Neither	The study had difficulty recruiting as the study focuses on a rare cancer type and has stringent inclusion and exclusion criteria

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68	17/YH/0387	230570	A Randomized Phase 3 Study of the Combination of Pembrolizumab (MK-3475) Plus Epacadostat (INCB024360) Alone or with Platinum-based Chemotherapy Versus Pembrolizumab Plus Platinum-based Chemotherapy Plus Placebo as First-Line Treatment in Patients with Metastatic Non-Small Cell Lung Cancer	05/03/2018	28/03/2018	03/01/2018	15/02/2018	29/03/2018	03/04/2018	09/04/2018	Please select	
69	17/YH/0388	235066	A multi-center, double-blind, randomized, placebo-controlled study to assess the pharmacodynamics, pharmacokinetics, tolerability, and safety of a single subcutaneous injection of ACT-246475 in adults with stable coronary artery disease	12/03/2018	09/04/2018	19/12/2017	11/04/2018	19/04/2018	20/04/2018	10/05/2018	Please select	
70	17/YH/0123	203556	International phase I/II expansion trial of the MEK inhibitor selumetinib in combination with dexamethasone for the treatment of relapsed/refractory RAS-pathway mutated paediatric and adult Acute Lymphoblastic Leukaemia	19/03/2018	19/03/2018	20/12/2017	29/03/2018	13/04/2018	13/04/2018	14/05/2018	Please select	
71	17/NE/0351	235420	A PERFORMANCE EVALUATION STUDY OF ARQUER'S MCM5 ELISA TEST TO AID IN THE DIAGNOSIS OF PROSTATE CANCER	26/03/2018	26/03/2018	02/01/2018	28/03/2018	09/04/2018	09/04/2018	24/04/2018	Please select	
72	18/SW/0086	242020	Home Assessment of urinary voiding and storage function before and After Radical Prostatectomy for prostate cancer: setting patient expectations (The HAARP study)	16/04/2018	23/04/2018	05/04/2018	23/04/2018	23/04/2018	23/04/2018	10/05/2018	Please select	
73	17/NE/0131	220721	Treating VISual hallucinations in people with MACular Degeneration: a non-invasive stimulation study	29/03/2018	29/03/2018	28/06/2017	04/04/2018	04/04/2018	04/04/2018	01/05/2018	Please select	
74	17/EE/0401	224915	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Assess the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Crohn's Disease Who Failed Prior Biologic Treatment	25/04/2018	25/04/2018	28/11/2017	29/04/2018	08/05/2018	08/05/2018		Neither	The sponsor agreed to have target of zero for this study so they can register and get their license in the UK. No eligible patient has been identified
75	17/EE/0400	224645	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Crohn's Disease	25/04/2018	25/04/2018	28/11/2017	26/04/2018	08/05/2018	08/05/2018		Neither	This study has a difficult eligibility criteria and a long washout period no patient has been identified
76	18/NE/0021	234187	A Phase 1, Open-Label, Parallel Group Study to Determine the Pharmacokinetics, Safety and Tolerability of Rucaparib in Patients with an Advanced Solid Tumor and either Moderate Hepatic Impairment or Normal Hepatic Function	19/03/2018	09/04/2018	23/03/2018	25/04/2018	11/05/2018	15/05/2018		Both	During setup there were NHS financial queries with the contract causing the study to be delayed. Eligible participants sought but not identified due to the strict participant eligibility criteria

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77	16/EE/0324	203951	A Phase II Prospective Trial of Prophylactic Donor Lymphocyte Infusions for the Prevention of Relapse post HSCT in patients with High Risk Myeloid Malignancy	23/05/2018	23/05/2018	08/09/2018	24/05/2018	24/05/2018	24/05/2018		Neither	Three eligible participants were seen but declined during the reported period. This was due to the eligibility criteria of the trial requiring a repeat bone marrow biopsy
78	16/WS/0165	190574	A Randomised Phase II study of Accelerated, Dose escalated, Sequential Chemo-radiotherapy in Non-small Cell Lung Cancer.	24/04/2018	24/04/2018	13/02/2018	27/04/2018	16/05/2018	16/05/2018	28/09/2018	Neither	Although lung MDT lists were screened by the PI from the opening of the study there were no potentially eligible patients until 11/JUL/2018
79	17/EM/0412	234907	An adaptive seamless randomized, double-blind, placebo-controlled, dose ranging study to investigate the efficacy and safety of LNP023 in primary IgA nephropathy patients	12/03/2018	04/04/2018	19/12/2017	16/04/2018	30/04/2018	02/05/2018		Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population
80	17/EE/0504	237721	A Randomized Controlled Trial with Resolute Onyx in One Month Dual Anti Platelet Therapy for High-Bleeding Risk Patients	30/04/2018	30/04/2018	20/03/2018	15/05/2018	22/05/2018	22/05/2018	09/06/2018	Please select	
81	18/NW/0105	239560	Electrical COUpling Information From The Rhythmia™ HDx Mapping System And DirecSense™ Technology In The Treatment Of Paroxysmal Atrial Fibrillation- A Non-Randomized, Prospective Study	24/04/2018	24/04/2018	13/03/2018	26/04/2018	16/05/2018	16/05/2018	29/06/2018	Please select	
82	18/NE/0040	237542	Feeding Late and Moderately Preterm Infants Nutrition and Growth Outcomes (FLAMINGO)	18/05/2018	18/05/2018	11/04/2018	22/05/2018	22/05/2018	22/05/2018	25/05/2018	Please select	
83	17/EE/0040	222216	Emergency Cerclage in Twin pregnancies at Imminent Risk of Preterm Birth: an Open-Label Randomised Controlled Trial	02/05/2018	02/05/2018	18/04/2017	02/05/2018	02/05/2018	02/05/2018		Sponsor	The team are still awaiting the green light from the sponsor as they will only issue this after the SIV has been completed
84	17/EM/0361	234065	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study in Subjects With Relapsing Multiple Sclerosis to Evaluate the Efficacy and Safety of BIIB033 as an Add-On Therapy to Anti-Inflammatory Disease-Modifying Therapies (AFFINITY)	26/04/2018	26/04/2018	11/01/2018	26/04/2018	09/05/2018	09/05/2018	20/08/2018	Neither	No suitable patients were identified at first as the study has very specific inclusion / exclusion criteria
85	18/LO/0112	238122	A Phase 3b, Multicenter, Open-Label Study to Evaluate Switching from an Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Fixed-Dose Combination Regimen or a Tenofovir Disoproxil Fumarate Containing Regimen to Fixed-Dose Combination of Bictegravir/Emtricitabine/Tenofovir Alafenamide in Elderly, Virologically-Suppressed, HIV-1 Infected Subjects Aged ≥ 65 Years	25/04/2018	25/04/2018	06/04/2018	26/04/2018	08/05/2018	08/05/2018	16/05/2018	Please select	
86	17/EE/0347	201505	A phase II randomised placebo controlled double blinded trial of Interleukin 1 blockade in Acute Severe Colitis	30/04/2018	30/04/2018	17/10/2017	01/05/2018	15/05/2018	15/05/2018	24/07/2018	Neither	Delays were caused by none of the identified patients being suitable for the trial

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87	17/LO/1461	230430	A Phase IIB, randomised, observer-blind, placebo-controlled, multi-centre study to evaluate the efficacy, safety, reactogenicity and immunogenicity of the GSK Biologicals' investigational vaccine GSK3277511A when administered intramuscularly according to a 0, 2 months schedule in COPD patients aged 40 to 80 years with a previous history of acute exacerbation (AECOPD).	12/02/2018	28/02/2018	10/10/2017	25/04/2018	04/05/2018	04/05/2018	16/05/2018	Sponsor	Initial delays were caused with the contract due to query resolutions with the sponsor. Once the study was approved there was also a delay in receiving green light from the sponsor
88	18/NW/0247	235344	A Feasibility Study: Is 'Pactster' a useful tool to increase exercise participation in the Adult Cystic Fibrosis Community?	31/05/2018	31/05/2018	14/05/2018	31/05/2018	31/05/2018	31/05/2018	20/06/2018	Please select	
89	17/NW/0529	226070	The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial	25/04/2018	25/04/2018	05/12/2017	02/05/2018	25/05/2018	25/05/2018	20/06/2018	Please select	
90	17/NW/0130	190157	An open non-randomised pilot study to assess acceptability and feasibility of an internet / mobile phone enhanced service pathway for the prevention and management of type 2 diabetes.	19/06/2017	02/05/2018	18/06/2018	28/06/2018	28/06/2018	28/06/2018	19/07/2018	Sponsor	The study took 57 days to approve because a major substantial amendment had to be passed by the sponsor during the initial study setup. This amendment needed several approvals, along with signing of the contracts and led to a substantial delay in study setup. There was also a delay in recruiting the first patient due to the study information not being sent out in time for participants to fully understand the study
91	17/EE/0402	224923	A Multicenter, Randomized, Double-Blind, Placebo Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease Who Responded to Induction Treatment in M16-006 or M15-991 Incorporating Administrative Change 1 and Amendment 1 and 2	29/05/2018	29/05/2018	28/11/2017	12/06/2018	28/06/2018	28/06/2018		Sponsor	Changes in the documentation for the study have impacted timelines. The study is still not open to recruitment
92	16/WS/0197	186191	An adaptive multi-arm phase II trial of maintenance targeted therapy after chemotherapy in metastatic urothelial cancer	27/11/2017	18/06/2018	01/02/2017	30/05/2018	27/06/2018	29/06/2018		Both	Sponsor was awaiting correctly completed study documents from the Trust. Documents were provided to sponsor in August. Sponsor then gave the green light on 11/9/18. No patients have been seen who fit the eligibility criteria
93	17/LO/0023	215490	MUK nine b: OPTIMUM. A phase II study evaluating multiple novel agents/optimised combination of biological therapy in newly diagnosed high risk multiple myeloma and plasma cell leukaemia.	22/06/2018	22/06/2018	30/03/2017	31/05/2018	26/06/2018	26/06/2018		NHS Provider	There was a delay in opening this trial as the lead pharmacist did not attend the SIV and required training before the sponsor could authorise opening to recruitment
94	18/EE/0023	231258	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis	08/05/2018	08/05/2018	21/03/2018	29/05/2018	14/06/2018	14/06/2018		Sponsor	Pharmacy queries regarding the exit strategy of the study took a little bit of time to resolve with the sponsor. This study deals with a rare cohort of patients and no eligible patient has been seen who fits the criteria

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95	17/LO/1918	229435	Does Neuromuscular Electrical Stimulation Improve the Absolute Walking Distance in Patients with Intermittent Claudication (NESIC) compared to best available treatment? A Multicentre Randomised Controlled Study.	09/02/2018	12/03/2018	29/01/2018	17/05/2018	11/06/2018	14/06/2018	06/07/2018	Sponsor	Long contracting delays with the sponsor caused the study to be approved late
96	18/NE/0076	242426	Pilot study: Endometabolic determinants of Unintentional weight Loss and frailty in Old age	19/06/2018	19/06/2018	24/04/2018	19/06/2018	19/06/2018	19/06/2018	14/09/2018	Neither	After approval it took 1 month for primary care practices who previously shown interest to collaborate in this study to find a date for site initiation and sending invites (primary care is the screening and recruitment sites). Recruitment started on 26th July 2018. Letters were processed and replies received but unfortunately only 1 reply was received. The PI arranged for this participant to attend the GP practice for screening, but the participant could only attend the screening in September
97	18/NE/0063	237090	Alpha Defensin use in Periprosthetic Joint Infection revision surgery	31/03/2018	01/04/2018	23/03/2018	01/04/2018	01/04/2018	01/04/2018	20/04/2018	Please select	
98	17/YH/0386	233803	The Cryo AF Global Registry is a prospective, global, multi-center, observational post-market registry	26/03/2018	22/05/2018	07/11/2017	24/05/2018	11/06/2018	14/06/2018	20/09/2018	Neither	Strict patient eligibility criteria caused patients to fail screening
99	18/NE/0173	241935	Targeting the Skeletal Muscle pump to Aid Standing in Elders with postural hypotension	05/06/2018	12/06/2018	14/05/2018	14/06/2018	14/06/2018	14/06/2018	13/09/2018	NHS Provider	Delay to recruitment of the first patient was due to staff obtaining (Disclosure and Barring Service) DBS approval due to incorrect documentation
100	18/NE/0035	237518	A Phase 2, Multi-center, Randomized, Placebo Controlled, Double-Blind Study with LJPC-401 for the Treatment of Iron Overload in Adult Patients with Hereditary Hemochromatosis	06/06/2018	06/06/2018	22/03/2018	30/05/2018	13/06/2018	13/06/2018	11/09/2018	Neither	Due to the intensity of this study (patients need to come in every week for 12 weeks) several people have refused to consent to the study. Two patients have already screen failed and another 2 refused due the cardio risk mentioned in the PIS
101	18/NW/0075	229477	A Phase 2a, Randomised, Partially-blind, Placebo-controlled Study to Assess the Efficacy, Safety, and Pharmacokinetics of 24 Weeks of Treatment With Multiple Doses of JNJ-56136379 as Monotherapy and in Combination With a Nucleos(t)ide Analogue in Subjects With Chronic Hepatitis B Virus Infection	29/05/2018	07/06/2018	06/03/2018	07/06/2018	21/06/2018	26/06/2018	25/09/2018	Neither	First patient was consented but unfortunately there was a mix-up in the lab. There have also been significant issues throughout recruitment with limitations to the numbers of patients allowed to be recruited to particular arms of the study, and limitations to the number of screening slots available at any one time. They have also brought forward some arms closing which has meant that the team haven't been able to get patients into the study
102	17/SC/0533	205320	A PHASE II STUDY OF ATEZOLIZUMAB WITH RITUXIMAB, GEMCITABINE AND OXALIPLATIN IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA WHO ARE NOT CANDIDATES FOR HIGH-DOSE THERAPY.	04/06/2018	12/06/2018	31/01/2018	13/06/2018	27/06/2018	29/06/2018	16/08/2018	Please select	
103	18/SC/0009	238195	An Open Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects with Primary Biliary Cholangitis (PBC)	16/04/2018	01/05/2018	22/02/2018	05/05/2018	31/05/2018	01/06/2018	18/06/2018	Both	The study had a few queries that took a few more days to resolve than usual, hence the study missed the 30 day benchmark
104	17/EE/0382	220851	PRedicting Outcomes For Crohn's disease using a moLecular biomarker (PROFILE) trial	22/05/2018	22/05/2018	02/11/2017	22/05/2018	04/06/2018	04/06/2018	07/09/2018	Neither	Participants were sought and screened but none were suitable for the trial

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105	17/WA/0242	228068	Prostatic Urethral Lift in Subjects with Acute Urinary Retention Study	06/05/2018	21/05/2018	01/08/2017	22/05/2018	31/05/2018	01/06/2018	04/06/2018	Please select	
106	17/EM/0122	224376	A PHASE 3, OPEN-LABEL, MULTICENTER STUDY OF ALXN1210 IN CHILDREN AND ADOLESCENTS WITH ATYPICAL HEMOLYTIC-UREMIC SYNDROME (aHUS)	25/09/2017	06/10/2017	30/05/2017	10/10/2017	25/10/2017	25/10/2017		Neither	This is a joint study with the renal team recruiting adolescents and adults. Our patient group is made smaller because the age range is 12 to 16 years. It is a rare condition and we have not yet had a patient presenting with the condition
107	17/LO/0736	225746	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Intravenously Administered BMS-986168 in Participants with Progressive Supranuclear Palsy	13/11/2017	13/11/2017	21/07/2017	16/11/2017	23/11/2017	23/11/2017	13/02/2018	Sponsor	Delays were caused by a change in the sponsor and new contracts needing to be supplied. Also the sponsor was awaiting pharmacy confirmation that all processes were in place before starting the study
108	17/WS/0165	226413	A Single Arm, Open Label, Multicenter Study to Evaluate the Efficacy and Safety of Glecaprevir(GLE)/Pibrentasvir(PIB) in Treatment Naïve Adults with Chronic Hepatitis C Virus (HCV) Genotypes 1 – 6 Infection and Aspartate aminotransferase to Platelet Ratio Index (APRI) ≤ 1	02/10/2017	02/10/2017	19/09/2017	20/10/2017	03/11/2017	03/11/2017	15/11/2017	Please select	
109	17/LO/1313	224703	Proton Pump Inhibitors vs. Histamine-2 Receptor Blockers for Ulcer Prophylaxis Therapy in the Intensive Care Unit (PEPTIC) study: A cluster randomised, crossover, registry-embedded clinical trial of proton pump inhibitors vs. histamine-2 receptor blockers for ulcer prophylaxis therapy in the Intensive Care Unit	12/12/2017	12/12/2017	11/10/2017	12/12/2017	19/12/2017	19/12/2017	03/01/2018	Please select	
110	18/NE/0037	211628	The feasibility of respiratory muscle training as part of an interstitial lung disease pulmonary rehabilitation programme	02/07/2018	02/07/2018	04/04/2018	02/07/2018	02/07/2018	02/07/2018	24/07/2018	Please select	
111	17/ES/0107	231506	A Phase 2 single arm study of Safety and Efficacy of Coversin in adult aHUS subjects.	18/05/2018	13/06/2018	14/09/2017	02/07/2018	25/07/2018	27/07/2018		NHS Provider	Initials delays were caused by the NHS provider regarding signature of contract. This is a study involving patients with atypical Haemolytic Uraemic Syndrome (aHUS) which is an extremely rare disease. Due to the rare nature of the disease it is difficult to predict when patients will present with the disease
112	18/NE/0052	234786	A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study to Evaluate the Safety and Efficacy of Avacopan (CCX168) in Patients with C3 Glomerulopathy	18/05/2018	12/06/2018	24/04/2018	22/06/2018	04/07/2018	06/07/2018	19/09/2018	Neither	This is a study involving patients with C3 Glomerulopathy which is an extremely rare disease. Due to the rare nature of the disease it was difficult to predict when patients would present with the disease
113	17/WS/0120	225090	A multi-center, double-blind, placebo-controlled, Phase 4 study in patients with pulmonary arterial hypertension to assess the effect of selexipag on daily life physical activity and patient's self-reported symptoms and their impacts.	29/05/2018	25/06/2018	24/07/2017	03/07/2018	13/07/2018	13/07/2018	10/09/2018	Sponsor	Delay in recruiting first patient was down to sponsor resolving Wi-Fi issues.

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114	18/LO/0739	238481	A pilot study investigating the usability of a mobile phone app to optimise the management of acne in primary care	10/07/2018	10/07/2018	01/05/2018	11/07/2018	11/07/2018	11/07/2018	06/09/2018	Please select	
115	18/NE/0104	241180	A Phase 3, Randomised, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)	06/06/2018	06/06/2018	02/05/2018	12/06/2018	06/07/2018	06/07/2018	18/07/2018	Please select	
116	18/SW/0049	237051	A Multicenter, Open-Label, Phase 1B/2 Study to Evaluate Safety and Efficacy of Avelumab (MSB0010718C) in Combination with Chemotherapy with or without Other Anti-Cancer Immunotherapies as First-Line Treatment in Patients with Advanced Malignancies	27/06/2018	10/07/2018	08/05/2018	20/07/2018	25/07/2018	27/07/2018	01/09/2018	Please select	
117	17/WA/0065	216267	The LIFT Trial - Lessening the impact of fatigue in inflammatory rheumatic diseases.	03/07/2018	03/07/2018	23/02/2018	04/07/2018	13/07/2018	13/07/2018	04/09/2018	Please select	
118	18/NW/0006	237093	Assessment of safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of the combination of GLPG2451 and GLPG2222, with or without GLPG2737, in adult subjects with cystic fibrosis	26/06/2018	26/06/2018	30/04/2018	22/06/2018	02/07/2018	02/07/2018	11/07/2018	Please select	
119	17/NE/0358	220871	Relative bioavailability and comparative pharmacokinetics of 13-CRA oral liquid and extracted capsule formulations: a randomised, open label, multi-dose, cross-over clinical trial in patients requiring treatment cycles of 13-CRA.	27/07/2018	27/07/2018	04/01/2018	23/08/2018	23/08/2018	24/08/2018	17/09/2018	Please select	
120	18/NE/0213	231323	Contractility: Cuff Versus Urodynamics Testing In Males With Voiding Lower Urinary Tract Symptoms	20/08/2018	20/08/2018	03/07/2018	20/08/2018	28/08/2018	28/08/2018	13/09/2018	Please select	
121	17/NW/0352	226135	A randomised controlled trial of the effectiveness, and cost-effectiveness, of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for trauma.	04/06/2018	25/07/2018	10/08/2017	08/08/2018	10/08/2018	15/08/2018		Neither	There have not been any eligible patients seen during the reporting period as patients need to be internally hemorrhaging in order to be suitable for the study
122	18/WM/0039	236159	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease who Completed the Studies M14-431 or M14-433	01/08/2018	01/08/2018	28/03/2018	03/08/2018	13/08/2018	13/08/2018		Please select	

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123	17/WM/0282	225240	A RANDOMIZED, OPEN-LABEL, ACTIVE CONTROLLED, SAFETY AND EXTRAPOLATED EFFICACY STUDY IN PEDIATRIC SUBJECTS REQUIRING ANTICOAGULATION FOR THE TREATMENT OF A VENOUS THROMBOEMBOLIC EVENT	18/05/2018	26/06/2018	21/11/2017	13/08/2018	10/08/2018	14/08/2018		Sponsor	Initial delays were caused by sponsor not able to sign the contract in time. Then the sponsor took a long time to arrange the SIV which caused problems with opening the study to recruitment
124	18/NE/0033	239296	Utilizing Novel Dipole Density Capabilities to Objectively Visualize the Etiology of Recurrent Atrial Fibrillation Following a Failed AF Ablation	14/05/2018	17/07/2018	27/02/2018	25/07/2018	09/08/2018	13/08/2018	13/09/2018	Please select	
125	18/NE/0179	241661	Is a very low calorie diet an acceptable therapy to achieve a target weight loss in patients with advanced non-alcoholic fatty liver disease?	06/08/2018	09/08/2018	30/07/2018	23/08/2018	28/08/2018	30/08/2018		Please select	
126	18/NE/0132	242937	A PHASE III, RANDOMIZED, MULTICENTER, OPEN-LABEL, TWO-ARM STUDY TO EVALUATE THE PHARMACOKINETICS, EFFICACY, AND SAFETY OF SUBCUTANEOUS ADMINISTRATION OF THE FIXED-DOSE COMBINATION OF PERTUZUMAB AND TRASTUZUMAB & CHEMOTHERAPY IN PATIENTS WITH HER2 POSITIVE EARLY BREAST CANCER	02/06/2018	06/08/2018	04/06/2018	17/08/2018	23/08/2018	24/08/2018	14/09/2018	Please select	
127	17/YH/0426	231118	A Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Dupilumab Administered Concomitantly with Topical Corticosteroids in Patients, ≥6 Years to <12 Years Of Age, with Severe Atopic Dermatitis	08/08/2018	08/08/2018	24/01/2018	09/08/2018	17/08/2018	17/08/2018		Please select	
128	18/WA/0154	233884	WHITE 8 COPAL: A Randomised Controlled Trial of low dose single antibiotic loaded cement versus high dose dual antibiotic loaded cement in patients receiving a hip hemiarthroplasty after fracture.	18/07/2018	31/07/2018	10/05/2018	07/08/2018	17/08/2018	22/08/2018	07/09/2018	Please select	
129	18/LO/1125	247338	Long-term, Open-label Extension Study for Patients with Duchenne Muscular Dystrophy Enrolled in Clinical Trials Evaluating Casimersen or Golodirsen	06/08/2018	06/08/2018	17/08/2018	24/08/2018	23/08/2018	24/08/2018	30/08/2018	Please select	
130	18/SW/0023	238640	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study, with an Active-Treatment Dose-Blinded Period, to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of BLB054 in Subjects with Parkinson's Disease.	13/09/2018	13/09/2018	01/05/2018	26/09/2018	26/09/2018	27/09/2018		Please select	

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131	18/LO/0229	239401	A Phase 1/2 open-label, multi-centre, safety, preliminary efficacy and pharmacokinetic (PK) study of isatuximab (SAR650984) in combination with REGN2810 or isatuximab alone in patients with advanced malignancies	29/08/2018	29/08/2018	24/04/2018	04/09/2018	11/09/2018	11/09/2018		Please select	
132	18/LO/0543	242259	An open-label Phase I/IIa study to evaluate the safety and efficacy of CCS1477 as monotherapy and in combination, in patients with advanced solid/metastatic tumours.	28/08/2018	28/08/2018	12/06/2018	31/08/2018	11/09/2018	11/09/2018		Please select	
133	18/NE/00/29	240385	A Phase 2, Open-label, Multicenter Study to Investigate the Efficacy, Safety, and Pharmacokinetics of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Patients with Previously Treated Hepatocellular Unresectable Carcinoma	05/09/2018	05/09/2018	10/05/2018	14/09/2018	19/09/2018	19/09/2018		Please select	
134	17/LO/1730	232371	A single arm, open-label, multi-centre, phase I/II study evaluating the safety and clinical activity of AUTO4, a CAR T cell treatment targeting TRBC1, in patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin lymphoma.	04/06/2018	23/07/2018	01/02/2018	21/08/2018	29/08/2018	04/09/2018		Please select	
135	17/LO/0731	219463	A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost	06/08/2018	06/08/2018	27/07/2017	13/09/2018	17/09/2018	17/09/2018		Sponsor	Initial delays were caused by sponsor querying the contract
136	18/LO/0858	241447	A PHASE II, RANDOMIZED, ACTIVE-CONTROLLED, MULTI-CENTER STUDY COMPARING THE EFFICACY AND SAFETY OF TARGETED THERAPY OR CANCER IMMUNOTHERAPY GUIDED BY GENOMIC PROFILING VERSUS PLATINUM-BASED CHEMOTHERAPY IN PATIENTS WITH CANCER OF UNKNOWN PRIMARY SITE WHO HAVE RECEIVED THREE CYCLES OF PLATINUM DOUBLET CHEMOTHERAPY	03/09/2018	11/09/2018	12/07/2018	14/09/2018	21/09/2018	25/09/2018		Please select	
137	18/NE/0172	247142	Pilot Study of ALLN-177 in Adult and Pediatric Subjects Aged 12 Years or Older with Enteric or Primary Hyperoxaluria and Hyperoxalemia	03/08/2018	05/09/2018	29/06/2018	07/09/2018	21/09/2018	27/09/2018		Please select	
138	17/SC/0070	215616	The Prepare Multi-Morbid Older People for End-stage Kidney Disease Trial	09/08/2018	23/08/2018	23/03/2018	23/08/2018	10/09/2018	11/09/2018		Please select	
139	18/WS/0087	241031	Optimal duration of Cooling therapy in Mild Encephalopathy (COMET 1)	28/08/2018	12/09/2018	18/06/2018	12/09/2018	13/09/2018	13/09/2018		Please select	

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140	17/LO/1649	228397	Phase 3, Open Label, Single Arm, Single Dose Gene Replacement Therapy Clinical Trial for Patients with Spinal Muscular Atrophy Type 1 with One or Two SMN2 Copies Delivering AVXS 101 by Intravenous Infusion	29/08/2018	29/08/2018	15/06/2018	31/08/2018	11/09/2018	11/09/2018		Please select	
141	17/EE/0474	229785	An Open-Label, Randomized, Multi-Center, Parallel Group, Two-Arm Study to Assess the Safety, Overall Tolerability, and Antiviral Activity of Brincidofovir versus Standard of Care for Treatment of Adenovirus Infections in High-Risk Pediatric Allogeneic Hematopoietic Cell Transplant Recipients.	13/09/2018	13/09/2018	06/02/2018	13/09/2018	24/09/2018	24/09/2018		Please select	
142	18/LO/0227	228539	A feasibility study of acceptance and COMMITment therapy for people with Motor nEuroN Disease (COMMEND)	23/08/2018	23/08/2018	13/03/2018	07/09/2018	25/09/2018	25/09/2018		Please select	
143	16/EM/0461	213043	Improving identification of familial hypercholesterolaemia in primary care using a new case ascertainment tool (FAMCAT)	06/08/2018	28/08/2018	03/02/2017	22/08/2018	11/09/2018	11/09/2018		Please select	
144	16/NE/0008	170481	Evaluation of Efficacy, Outcomes and Safety of a New Infant Haemodialysis and Ultrafiltration Machine in Clinical Use.	09/07/2018	25/07/2018	19/04/2018	31/07/2018	31/07/2018	31/07/2018		Neither	Delays have been caused as the contract has not yet been signed with Allmed who is supplying the device for the study
145	17/WM/0445	236707	A two-part randomized, double-blind, placebo-controlled multicenter dose ranging and confirmatory study to assess the safety and efficacy of VAY736 in autoimmune hepatitis patients with incomplete response to or intolerance of standard therapy(AMBER)	21/05/2018	09/07/2018	16/01/2018	13/07/2018	25/07/2018	27/07/2018		Neither	This study has a difficult inclusion criteria no eligible patient have been seen during the relevant period
146	18/WM/0038	235048	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Conventional Therapies but Have Not Failed Biologic Therapy.	18/06/2018	18/06/2018	26/03/2018	04/07/2018	16/07/2018	16/07/2018		Neither	This study is difficult to recruit to due to standard medication being already available
147	18/WM/0037	228917	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease who have inadequately Responded to or are Intolerant to Biologic Therapy	18/06/2018	18/06/2018	26/03/2018	04/07/2018	16/07/2018	16/07/2018		Neither	This study deals with a difficult recruitment cohort. Patients have to stop current treatment for 12 weeks before they can be screened. No patient has been identified

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148	18/NE/0003	236908	GCT 1029-01- First-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety of GEN1029 in patients with malignant solid tumors	30/05/2018	30/05/2018	29/03/2018	13/06/2018	02/07/2018	02/07/2018	14/08/2018	Neither	This is a slot driven, dose escalation study. No slot/participant was available until mid August
149	18/NI/0084	239210	A Phase 3 Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Daily Subcutaneous Injections of Elamipretide in Subjects with Primary Mitochondrial Myopathy Followed by an Open-Label Treatment Extension	09/07/2018	18/07/2018	26/06/2018	24/07/2018	09/08/2018	13/08/2018		Sponsor	After approval it took 1 month for primary care practices who previously shown interest to collaborate in this study to find a date for site initiation and sending invites (primary care is the screening and recruitment sites). Recruitment started on 26th July 2018. Letters were processed and replies received but unfortunately only 1 reply was received. The PI arranged for this participant to attend the GP practice for screening, but the participant could only attend the screening in September
150	17/NE/0386	234030	BIOlogical Factors that Limit sustAined Remission in rhEumatoid arthritis (the BIO-FLARE study)	31/05/2018	12/06/2018	23/02/2018	21/06/2018	21/06/2018	21/06/2018	11/09/2018	Neither	Delays to recruitment were caused because of the tight inclusion and exclusion criteria