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/LO/0232	220795	A Three-Part Open Label Titration, Open Label Randomized Crossover, and Double Observer Single-Blind, Superiority Trial of APL-130277 compared to S.C. Apomorphine in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations	18/04/2017	18/04/2017	23/03/2017	24/04/2017	24/04/2017	24/04/2017		Sponsor	Sponsor delayed opening of the study due to several changes in the protocol. They believed these changes would result in a more scenically robust study, in line with EMA recommendations. No patient has been seen who suited the study criteria
2	17/NE/0095	219254	Improving Parkinson's Related Overactive Bladder	24/04/2017	24/04/2017	20/04/2016	08/05/2017	08/05/2017	08/05/2017	10/05/2017	Please select	
3	17/EM/0116	222773	A Multicenter, Open-Label Study to Evaluate the Safety and Tolerability of Tozadenant as Adjunctive Therapy in Levodopa-Treated Patients with Parkinson's Disease Experiencing End of Dose "Wearing-Off"	02/05/2017	02/05/2017	04/04/2017	22/05/2017	22/05/2017	22/05/2017		Sponsor	The Green Light was late coming from sponsor because of the non-standardised method of performing 6 minute walk tests. No patient has been seen who meets the criteria of the study and then the sponsor closed the study due to the discontinuation of the Tozadenant Development Program
4	16/LO/2002	214578	A Double-Blind, Placebo-Controlled, Multicenter Study with an Open-Label Extension to Evaluate the Efficacy and Safety of SRP-4045 and SRP-4053 in Patients with Duchenne Muscular Dystrophy	21/04/2017	21/04/2017	25/01/2017	21/04/2017	09/05/2017	09/05/2017	14/06/2017	Please select	
5	16/SC/0484	208568	An Open Label, Randomized, Two Arm Phase III Study of Nivolumab in Combination with Ipilimumab versus Extreme Study Regimen (cetuximab + cisplatin/carboplatin + fluorouracil) as First Line Therapy in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	10/04/2017	10/04/2017	10/02/2017	17/05/2017	17/05/2017	17/05/2017	02/08/2017	Neither	This trial is a targeted immunotherapy versus an extreme chemotherapy regime. Patients must have documented PDL1 status and be ECOG Performance Status of 0-1 to be considered fit enough for the trial. There was no suitable patients identified in the 70 days either due to poor ECOG performance status or not having suitable lesions to be biopsied to document PDL1 Status
6	14/WM/1170	161147	Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer	25/05/2017	25/05/2017	26/05/2016	30/05/2017	30/05/2017	30/05/2017	28/02/2018	NHS Provider	This study took a while to open to recruitment as the research team were waiting for immunotherapy and surgical training before the sponsor would give them the green light. No eligible patient was seen in the 70 day window
7	16/NE/0384	209045	A multi-center, randomized, double-blind, active-controlled, parallelgroup Phase 3 study to evaluate the efficacy and safety of LCZ696 compared to ramipril on morbidity and mortality in patients with left ventricular dysfunction following an acute myocardial infarction	02/05/2017	02/05/2017	05/01/2017	25/05/2017	25/05/2017	25/05/2017	04/07/2017	Please select	
8	16/NE/0398	219462	Clinical Study of the BioVentrix Revivent TC™ System for Treatment of Left Ventricular Aneurysms	13/04/2017	13/04/2017	07/02/2017	08/05/2017	08/05/2017	08/05/2017	13/06/2017	Please select	
9	17/WA/0066	218686	Role of cardiac output in exercise capacity in patients with left ventricular assist devices	03/05/2017	03/05/2017	12/04/2017	03/05/2017	04/05/2017	04/05/2017	16/08/2017	Neither	No eligible participants were seen during the reported period who had been planted with the device

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10	16/SC/0462	208830	DRAFFT 2: Distal Radius Acute Fracture Fixation Trial - A Randomised Controlled Trial of Manipulation and surgical fixation with K-wires versus Manipulation and Casting in the Treatment of Adult Patients with a Dorsally Displaced Fracture of the Distal Radius	13/04/2017	13/04/2017	11/11/2017	18/04/2017	04/05/2017	04/05/2017	11/05/2017	Please select	
11	16/WM/0006	192580	WHIST - Wound Healing In Surgery for Trauma. A Randomised Controlled Trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients havin g surgical incisions for major trauma to the lower limb	24/04/2017	24/04/2017	26/08/2016	26/05/2017	26/05/2017	26/05/2017	19/06/2017	Please select	
12	16/EM/0240	203358	A Randomized, Open-label, Safety and Efficacy Study of Ibrutinib in Pediatric and Young Adult Patients With Relapsed or Refractory Mature B-cell non-Hodgkin Lymphoma	25/04/2017	25/04/2017	11/10/2016	24/04/2017	02/05/2017	02/05/2017		Neither	This is a very rare disease and no patients have presented in this time period
13	16/NW/0629	211995	The cystic fibrosis (CF) anti-staphylococcal antibiotic prophylaxis trial (CF START); a randomised registry trial to assess the safety and efficacy of flucloxacillin as a longterm prophylaxis agent for infants with CF.	19/04/2017	19/04/2017	22/09/2016	02/05/2017	02/05/2017	02/05/2017	18/10/2017	Neither	The CFSTART study did not recruited in the first 70 days simply due to the nature of the study and lack of eligible new born screened infants diagnosed with cystic fibrosis. This will be an issue across all sites as it is rare disease study
14	12/NW/0694	109044	A 12 week randomised, open-label, active control period followed by a 12 week safety extension period to evaluate the safety and efficacy of Fesoterdine in subjects aged 6 to 16 years and >25kg with symptoms of detrusor overactivity associated with a neurological condition (neurogenic detrusor overactivity)	18/04/2017	18/04/2017	12/10/2016	25/04/2017	05/05/2017	05/05/2017		Sponsor	The study did not hit the 70 day target because the sponsor was not able to answer some questions that the team required for use of the log pads which were to be provided to the patients. Also the ECG machine provided by the sponsor is not working and the site is not able to use their own. No patient has been seen to date
15	17/NE/0019	212701	SharkCore biopsy needle versus standard FNA needle in the diagnosis of solid pancreatic masses a randomised controlled cross-over trial of EUS guided tissue acquisition - The SharkBITE study	19/04/2017	19/04/2017	27/02/2017	19/04/2017	02/05/2017	02/05/2017	22/05/2017	Please select	
16	16/LO/0058	193773	LAVA- Liver Resection Surgery Versus Thermal Ablation for Colorectal LiVer MetAstases	25/04/2017	25/04/2017	22/08/2016	10/04/2017	04/05/2017	04/05/2017		Neither	The trial has specific inclusion criteria, Every patient discussed at the weekly HPB MDT is considered but so far none have met the inclusion criteria. We are liaising with other sites to see if we can learn from their experience. The team from the trial centre will are going to visit our site to observe our processes and see if they can advise

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17	16/NE/0200	196056	Conservative iron chelation as a disease-modifying strategy in Parkinson's disease.	27/04/2017	27/04/2017	22/08/2016	27/03/2017	27/06/2017	27/06/2017		Sponsor	Initial delays were caused by Sponsor querying aspects of the contract before signing. This study waiting a while for the Green Light from the sponsor for specific equipment to be used in the study. No patients have presented who matched the criteria for the study
18	16/NE/0325	199217	Eculizumab in Shiga-Toxin producing E. Coli Haemolytic Uraemic Syndrome (ECUSTEC): A Randomised, Double-Blind, Placebo-Controlled Trial	19/06/2017	19/06/2017	30/05/2017	30/06/2017	30/06/2017	30/06/2017	24/10/2017	Neither	This study covers a rare disease in patients. The first patient within the time frame, the parent declined to go into the study. The second lived abroad, (in Australia), and was not be able to cover the follow-up needed
19	16/NE/0386	217871	VBP15-002 A Phase IIa Open-Label, Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Exploratory Efficacy of Vamorolone in Boys with Duchenne Muscular Dystrophy (DMD)	24/05/2017	24/05/2017	24/05/2017	21/03/2017	12/06/2017	12/06/2017	29/06/2017	Please select	
20	16/NE/0387	218683	Amended Clinical Protocol #1 for a Phase II Open-label, Multicenter Extension Study to Assess the Long-term Safety and Efficacy of Vamorolone in Boys with Duchenne Muscular Dystrophy (DMD).	24/05/2017	24/05/2017	24/05/2017	21/03/2017	12/06/2017	12/06/2017	07/08/2017	Neither	The main study was very short and patients were only in it for 1 to 2 months. Submission of the extension study should have been delayed to try and ensure that patients would be rolling over within the target timeframe for recruiting the first patient, but with the main study being so short and in the interests of patients, I think we erred on the side of caution rather than run the risk of the extension study not being approved in time. Hence the first patient was not recruited until early Sept
21	17/EM/0006	216496	A Parallel Group, Double-Blind, Randomized, Placebo Controlled Phase 3 Trial to Evaluate the Efficacy and Safety of ALD403 Administered Intravenously in Patients with Chronic Migraine	06/06/2017	06/06/2017	02/05/2017	07/06/2017	15/06/2017	15/06/2017	04/07/2017	Please select	
22	16/WM/0507	218607	A randomized, double-blind, active control, multicenter study to evaluate the efficacy at week 52 of subcutaneously administered secukinumab monotherapy compared with subcutaneously administered adalimumab monotherapy in patients with active psoriatic arthritis	23/05/2017	23/05/2017	01/03/2017	30/05/2017	12/06/2017	12/06/2017	10/07/2017	Please select	
23	17/EE/0017	213606	A double-blind, placebo controlled, multicentre, clinical trial to investigate the efficacy and safety of 12 months of therapy with inhaled Promixin (colistimethate sodium) in the treatment of subjects with non-cystic fibrosis bronchiectasis chronically infected with Pseudomonas aeruginosa (P.aeruginosa)	18/05/2017	18/05/2017	24/02/2017	27/06/2017	27/06/2017	27/06/2017	07/11/2017	sponsor	Delayed SIV due to contractual issues and issues in regards to IMP accountability obstructed the research team from consenting and screening

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24	16/SC/0530	213306	Evaluating the tolerance, compliance, acceptability and safety of Ketocal 2.5:1 LQ, a nutritionally complete liquid feed for use as part of the Ketogenic Diet in children 8+ years, adolescents and adults with intractable epilepsy or other disorders where the KD is indicated	12/05/2017	12/05/2017	05/12/2016	02/06/2017	02/06/2017	02/06/2017	13/09/2017	Neither	It is a very small group of patients who will be eligible for the study. The first 2 patients were approached within the 70 day time frame but declined to participate
25	17/LO/0212	221502	An open label, active comparator extension trial to assess the effect of long term dosing of inclisiran and evolocumab given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C (ORION-3)	08/05/2017	08/05/2017	16/03/2017	02/06/2017	02/06/2017	02/06/2017	17/07/2017	Please select	
26	17/NE/0078	221507	A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Phase 2 Study to Evaluate the Efficacy and Safety of Elafibranor at Doses of 80 mg and 120mg after 12 Weeks of Treatment in Patients With Primary Biliary Cholangitis (PBC) and Inadequate Response to Ursodeoxycholic Acid.	22/05/2017	22/05/2017	22/05/2017	27/06/2017	27/06/2017	27/06/2017	07/08/2017	Neither	Screened patient had delayed entry into study due to pre-planned holiday commitments. Patient who enrolled did so on the last day of the 4 week screening period. If screening has been planned earlier, they could not have entered trial as their holiday was booked at this time
27	17/LO/0096	220205	A Phase 3b, 12-month, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of BIIB019, Daclizumab, in Subjects with Relapsing-Remitting Multiple Sclerosis (RRMS) Switching from Natalizumab (SUSTAIN)	12/05/2017	12/05/2017	17/01/2017	22/05/2017	01/06/2017	01/06/2017		Sponsor	Recruitment is temporarily suspended due to a case of fatal fulminant liver failure in a patient treated with the study drug. The temporary recruitment hold in the UK is provisional whilst the European Medicines Agency (EMA) Article 20 procedure is ongoing and is subject to change upon conclusion of the review. It is currently anticipated that the Pharmacovigilance Risk Assessment Committee (PRAC) will issue their recommendations by Sep 17 and the Article 20 procedure will be completed by Nov 17
28	17/WM/0017	201600	A randomised placebo-controlled trial of mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage	16/06/2017	16/06/2017	18/04/2017	27/06/2017	27/06/2017	27/06/2017	26/10/2017	Sponsor	There were problems with the sponsor's ECRF and randomisation website which was not working and therefore no patients could be recruited until this was sorted because all patients have to be randomised. This went live on the 29th September
29	16/LO/1987	207718	Clinical Monitoring and Biomarkers to stratify severity and predict outcomes in children with cystic fibrosis (CLIMB-CF). Complex Intervention Study Stage 1: Pilot and Feasibility assessment	30/05/2017	30/05/2017	19/12/2016	02/06/2017	02/06/2017	02/06/2017	26/09/2017	NHS Provider	The SIV was delayed because a key member of the team was off sick. It then took a little while to identify the patients following the SIV as the clinical team were very busy
30	17/SC/0028	218036	A Double-Blind, Randomized, Two Arm Phase 2 Study of Nivolumab in Combination with Ipilimumab versus Nivolumab in Combination with Ipilimumab Placebo In Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	26/05/2017	26/05/2017	09/02/2017	29/06/2017	29/06/2017	29/06/2017	19/07/2017	Please select	

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31	17/NI/0005	216105	A Cancer Research UK phase I trial of LY3143921 hydrate (a Cdc7 inhibitor) given orally once daily in adult patients with advanced solid tumours	05/06/2017	05/06/2017	17/02/2017	27/06/2017	27/06/2017	27/06/2017	06/10/2017	Neither	This is a 'rare' cancer and unfortunately no suitable patients who fulfilled the eligibility criteria for the study were referred to the principal investigator in the indicated time window
32	12/LO/1320	104290	Aneurysm Treatment using the HeliFX Aortic Securement System Global Registry	10/04/2017	10/04/2017	24/01/2017	13/04/2017	27/04/2017	27/04/2017	21/06/2017	Neither	Due to the cyber-attack we were unable to receive documents following the SIV which we didn't receive until the 31st May. We recruited the first patient 21 days after this. Patients can also only be identified by the Consultant / Radiologist for this specific endoanchor procedure
33	16/EM/0512	215840	A PHASE III, DOUBLE-BLINDED, RANDOMIZED, PLACEBO-CONTROLLED STUDY OF ATEZOLIZUMAB PLUS COBIMETINIB AND VEMURAFENIB VERSUS PLACEBO PLUS COBIMETINIB AND VEMURAFENIB IN PREVIOUSLY UNTREATED BRAFV600 MUTATION–POSITIVE PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC MELANOMA	18/04/2017	18/04/2017	06/09/2016	11/05/2017	11/05/2017	11/05/2017	06/02/2018	Neither	This is a targeted therapy and patients need to have previously untreated advanced/metastatic BRAF V600 mutation-positive melanoma. No such patients willing to participate were identified during this time period
34	15/SC/0565	174968	A Phase I/IIa Study of Targeted Radiotherapy alone for Stem Cell Transplant Conditioning in Systemic AL Amyloidosis	19/06/2017	12/07/2017	30/06/2017	17/07/2017	17/07/2017	17/07/2017		Neither	This is a 'rare' cancer and unfortunately no suitable patients who fulfilled the eligibility criteria for the study were referred to the principal investigator in the indicated time window
35	17/SC/0109	211188	An Open-Label, Dose-Finding and Proof of Concept Study of the PD-L1 Probody Therapeutic, CX-072, as Monotherapy and in Combination with Yervoy (Ipilimumab) or with Zelboraf (Vemurafenib) in Anti-PD-1/PD-L1 Inhibitor Naive Subjects with Advanced or Recurrent Solid Tumors or Lymphomas	06/07/2017	06/07/2017	02/03/2017	08/06/2017	19/07/2017	19/07/2017	11/08/2017	Please select	
36	17/NE/0093	222453	Preoperative Behavioural Intervention to Reduce Drinking before elective orthopaedic Surgery: A Pilot Randomised Controlled Trial	19/06/2017	19/06/2017	06/04/2017	07/07/2017	07/07/2017	07/07/2017	17/08/2017	Please select	
37	16/EE/0463	214371	An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced breast cancer (ABC) with no prior hormonal therapy for advanced disease	19/07/2017	19/07/2017	30/01/2017	14/07/2017	27/07/2017	27/07/2017	09/10/2017	Sponsor	Sponsor did not open the study until 25/08/2017 and the team did not see any suitable patient for the trial within the 70 day window

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38	17/LO/0243	219613	A randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of several repeat dose levels of GSK2330672 administration in patients with Primary Biliary Cholangitis (PBC) Pruritus	19/06/2017	19/06/2017	27/03/2017	28/06/2017	12/07/2017	13/07/2017	01/11/2017	Both	Multiple contracting problems between the Trust PI, Pharmacy, GCP, MHRA and Sponsor caused initial delays. The research team have pre-screened 240 patients and not one has been suitable. There has only been 2 patients recruited in the UK since the study commenced
39	17/LO/0402	209419	A PHASE III, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF ATEZOLIZUMAB (ANTI-PD-L1 ANTIBODY) AS ADJUVANT THERAPY IN PATIENTS WITH RENAL CELL CARCINOMA AT HIGH RISK OF DEVELOPING METASTASIS FOLLOWING NEPHRECTOMY	12/07/2017	12/07/2017	09/06/2017	13/06/2017	27/07/2017	27/07/2017		Sponsor	The clinical team received R&D approval on 27/07/17, however immediately after this a substantial amendment came through which required ICF change, this was only approved by R&D early September. No patients have been identified that met the criteria within the reporting period
40	16/WM/0437	206855	A Phase 3 Multicenter, Open-label, Randomized Study of Rucaparib versus Chemotherapy in Patients with Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	19/06/2017	19/06/2017	15/12/2015	14/07/2017	14/07/2017	14/07/2017	22/08/2017	Please select	
41	17/SC/0142	215503	Evaluating the clinical and cost-effectiveness of permissive hypotension in critically ill patients aged 65 years or over with vasodilatory hypotension	26/06/2017	26/06/2017	24/04/2017	27/07/2017	27/07/2017	27/07/2017	31/10/2017	Both	Due to lack of staff and constant re-prioritising the study was pushed pack so other studies could be finished. The sponsor also delayed given the Green Light
42	15/YH/0483	191668	Single Arm Study to Assess the Efficacy of UVADEX (methoxsalen) Sterile Solution in conjunction with the Therakos CELLEX Photopheresis system in Pediatric Patients with steroid-refractory Acute Graft versus Host Disease (aGvHD)	26/06/2017	26/06/2017	17/10/2016	11/08/2017	11/08/2017	11/08/2017	16/03/2018	Sponsor	Sponsors internal QC took 14 days which pushed the study over the 40 days. It is a very small group of patients who will be eligible for this study. They need to have undergone bone marrow transplant then develop acute graft versus host disease then fulfil the strict inclusion and exclusion criteria. No patient was identified in the 70 day window
43	17/EE/0071	201502	Direct Implantation of the SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System (IDS) with Bioresorbable Drug Carrier Technology The DIRECT III Post Market Study	31/07/2017	31/07/2017	27/04/2017	31/07/2017	09/08/2017	09/08/2017	15/09/2017	Please select	
44	16/SC/0391	208610	A randomized, double-blind, double-dummy, parallel-group study comparing the efficacy and safety of ofatumumab administered subcutaneously versus teriflunomide administered orally in patients with relapsing forms of multiple sclerosis	26/07/2017	26/07/2017	06/07/2016	02/08/2017	14/08/2017	14/08/2017		Sponsor	Due to fast Global recruitment the sponsor was able to close the study early. No patients were recruited at Newcastle
45	14/SC/0221	145869	A randomised phase II pilot study of 3 weekly Cabazitaxel versus weekly Paclitaxel chemotherapy in the first line treatment of HER2 negative metsastatic breast cancer	10/07/2017	27/07/2017	06/05/2016	02/08/2017	10/08/2017	15/08/2017	11/12/2017	Neither	This trial requires patients with Her2 negative metastatic breast cancer who will be eligible for trial if they are fit to receive chemotherapy in first line setting (ECOG performance status 0 or 1) and have measurable disease as per RECIST 1.1. There were no patients who were considered fit enough for the trial that also had measurable disease identified in the 70 days

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46	17/WM/0096	209809	A Randomised Controlled Trial of the Clinical and Cost Effectiveness of Low Level Laser in the Management of Oral Mucositis in Head and Neck Cancer Irradiation.	04/08/2017	04/08/2017	28/11/2017	11/08/2017	11/08/2017	11/08/2017		NHS Provider	The study has been unable to recruit due to a number of factors including a lack of trained staff to deliver the laser treatment
47	16/SC/0677	217105	A Phase 2, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Primary Biliary Cholangitis Without Cirrhosis	12/05/2017	12/05/2017	18/01/2017	07/08/2017	15/08/2017	21/08/2017		Both	The Contract and Budget did not match - Sponsor wanted to round up the totals and the trust would not except this. It took a long time for the Sponsor to agree the Trusts terms. The research team have been actively looking for patients but not identified anyone in clinic who fit the strict eligibility criteria. Study is now closed to recruitment and no patients were recruited at Newcastle
48	17/NE/0020	218494	A randomized, double blind (sponsor open), comparative, multicenter study to evaluate the safety and efficacy of subcutaneous belimumab (GSK1550188) and intravenous rituximab coadministration in subjects with primary Sjögren's syndrome.	10/07/2017	09/08/2017	20/03/2017	17/08/2017	25/08/2017	29/08/2017	28/12/2017	Neither	The Professor running this study has been actively approaching patients but no eligible participants were identified until after the 70 day window
49	16/SC/0676	217183	A Phase 2, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Subjects with Primary Sclerosing Cholangitis Without Cirrhosis	15/05/2017	15/05/2017	19/01/2017	07/08/2017	15/08/2017	21/08/2017		Both	The Contract and Budget did not match - Sponsor wanted to round up the totals and the trust would not except this. The clinical team have been actively looking for patients however, none have been identified in clinic who fit the criteria. The study was closed by the sponsor before a patient was found at Newcastle
50	17/SS/0052	196827	Early Valve Replacement guided by Biomarkers of Left Ventricular Decompensation in Asymptomatic Patients with Severe Aortic Stenosis	07/08/2017	07/08/2017	13/06/2017	23/08/2017	23/08/2017	23/08/2017	22/11/2017	NHS Provider	Prolonged difficulties with MRI software setup caused the study to miss the 70 day benchmark
51	15/LO/1950	184545	A Randomized Placebo Controlled Phase 2b/3 Study of ABT-414 in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification (Intellance 1)	17/07/2017	25/07/2017	18/01/2017	15/08/2017	25/08/2017	30/08/2017	22/09/2017	Please select	
52	17/LO/0591	218516	An open-label, first-in-human, dose-escalation study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and maximum tolerated dose and / or recommended Phase II dose of the ATR inhibitor BAY 1895344 in patients with advanced solid tumors and lymphomas	25/07/2017	25/07/2017	18/05/2017	10/08/2017	16/08/2017	16/08/2017	19/09/2017	Please select	

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53	17/EE/0079	220827	A Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the safety and efficacy of CCX168 in patients with anti-neutrophil cytoplasmic antibody (ANCA)- Associated Vasculitis Treated Concomitantly with Rituximab or Cyclophosphamise/ Azathioprine	03/07/2017	10/07/2017	06/04/2017	27/07/2017	07/08/2017	08/08/2017		Neither	This is a rare disease and unfortuantely no suitable patients who fulfilled the eligibility criteria for the study were refered to the prinical investigator in the indicated time window
54	16/SC/0566	213579	A MULTICENTRE CLINICAL INVESTIGATION OF MAGNETICALLY ENHANCED DIFFUSION FOR ACUTE ISCHEMIC STROKE (MEDIS)	02/06/2017	02/06/2017	10/01/2017	09/08/2017	09/08/2017	09/08/2017		Both	The trial had to go through the new intervention committee. The committee asked for a safety review and Clinical Governance were involved and safety barriers had to be constructed around equipment. This all had to be signed before Approval was given. The company then put a stop on recruitment while a safety issue was addressed (at another site who recruited a patient). The company still has a new protocol to be actioned. Sponsor decided to withdraw from this arm of their research
55	17/EM/0154	222912	A Multi-centre, Double-blind, Randomised, Placebo-controlled, Parallel-arm Phase IIa Trial to Evaluate the Efficacy, Safety and Tolerability of 28-Day Oral Treatment with PXT002331 (foliglurax) in Reducing Motor Complications of Levodopa Therapy in Subjects with Parkinson's Disease Experiencing End-of-dose Wearing Off and Levodopa-Induced Dyskinesia (AMBLED)	17/07/2017	20/07/2017	27/06/2017	01/08/2017	07/08/2017	30/08/2017	19/02/2018	Sponsor	This study is waited a long time to get the Green Light from the sponsor for specific equipment to be used in the study. Because of this delay the study missed the 70 day window and did not recruit their first patient until February 2018
56	17/NE/0193	221511	Phase II feasibility study of the efficacy and acceptability of a low residue diet in adult patients with mitochondrial disease.	14/08/2017	21/08/2017	04/07/2017	25/08/2017	25/08/2017	30/08/2017	30/08/2017	Please select	
57	17/LO/0169	214075	Effect of MD1003 in progressive multiple sclerosis: a randomized double blind placebo controlled study	24/07/2017	24/07/2017	21/04/2017	18/08/2017	29/08/2017	29/08/2017	23/10/2017	Neither	The study missed the 70 day target due to the strict participant eligibility inclusion criteria and we did not have the relevant referrals / patients in this time
58	16/SC/0542	208245	A multicener, Open-Label, Extension Study To Evaluate The Long-Term Safety And Tolerability Of Lampalizumab In Patients With Geographic Atrophy Secondary To Age-Related Macular Degeneration Who Have Completed A Roche-Sponsored Study.	14/08/2017	14/08/2017	09/11/2016	16/08/2017	29/08/2017	29/08/2017	06/09/2017	Please select	
59	17/LO/0683	226533	A Phase 2, Randomized, Double-blind, Controlled Study to Evaluate the Safety and Efficacy of VX-659 Combination Therapy in Subjects Aged 18 Years and Older With Cystic Fibrosis	14/08/2017	29/08/2017	14/08/2017	04/09/2017	11/09/2017	11/09/2017	26/09/2017	Please select	

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60	17/NI/0096	225743	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE II STUDY TO EVALUATE THE EFFICACY AND SAFETY OF SPX-101 INHALATION SOLUTION IN SUBJECTS WITH CYSTIC FIBROSIS (HOPE-1 STUDY: HYDRATION FOR OPTIMAL PULMONARY EFFECTIVENESS)	21/08/2017	07/09/2017	14/07/2017	14/09/2017	25/09/2017	26/09/2017	02/11/2017	Please select	
61	16/NE/0344	215891	A First-in-Human, Open-label, Phase 1/2 Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of JNJ-63723283, an Anti-PD-1 Monoclonal Antibody, in Subjects with Advanced Cancers	31/08/2017	31/08/2017	02/03/2017	06/09/2017	21/09/2017	21/09/2017	01/02/2018	Neither	Newcastle entered the study at Part 2 and the number of disease cohorts was drastically cut, leaving only melanoma. Due to restrictions on previous treatment no UK sites are likely to be able to recruit to this cohort. The team have recently implemented an amendment re-introducing further disease cohorts and we have 2 patients lined-up
62	17/NE/0149	224550	A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer (MERU)	14/08/2017	29/08/2017	19/06/2017	05/09/2017	19/09/2017	26/09/2017	07/12/2017	Neither	The study is a maintenance study that requires 4 cycles of chemotherapy and radiotherapy to the brain prior to randomisation. This treatment takes longer than the 70 day period before patients become eligible for the study
63	17/SC/0294	224828	Title: A Phase III Randomised Study to Investigate the Efficacy and Safety of Atezolizumab (Anti–PD-L1 Antibody) in Combination with Neoadjuvant Anthracycline/Nab-paclitaxel Based Chemotherapy Compared with Placebo and Chemotherapy in Patients with Primary Invasive Triple-Negative Breast Cancer	21/08/2017	07/09/2017	02/08/2017	11/09/2017	19/09/2017	27/09/2017	26/10/2017	Please select	
64	17/LO/0035	218519	Development and evaluation of an intervention to support Adherence to treatment in adults with Cystic Fibrosis. A randomised controlled trial and parallel process evaluation.	06/09/2017	06/09/2017	03/04/2017	13/09/2017	13/09/2017	13/09/2017	05/10/2017	Please select	
65	16/SC/0277	202191	Point Of Care Testing For Sepsis In ICU Patients: A Diagnostic Accuracy Study	07/08/2017	01/09/2017	18/10/2016	13/09/2017	25/09/2017	27/09/2017	29/09/2017	Please select	
66	16/YH/0452	130824	PHASE I-II STUDY OF VINBLASTINE IN COMBINATION WITH NILOTINIB IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH REFRACTORY OR RECURRENT LOW-GRADE GLIOMA	14/08/2017	29/08/2017	09/12/2016	14/09/2017	22/09/2017	26/09/2017	02/10/2017	Please select	
67	17/LO/0779	224562	Phase Ib /II Clinical Trial of Nivolumab Monotherapy and Nivolumab in Combination with Ipilimumab in Pediatric Subjects with High Grade Primary CNS Malignancies	28/08/2017	08/09/2017	11/07/2017	12/09/2017	25/09/2017	26/09/2017	19/10/2017	Please Select	

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68	16/NE/0363	215166	A randomized, double-blind, placebo-controlled, multicenter, dose-range, proof-of-concept, 24-week treatment study of IVA337 in adult subjects with nonalcoholic steatohepatitis (NASH).	30/08/2017	30/08/2017	13/02/2017	07/09/2017	21/09/2017	21/09/2017	27/11/2017	Neither	The NATIVE study did not recruited in the first 70 days due to tight eligibility, particularly relating to heart disease and/or type 1 diabetes
69	17/LO/0848	222163	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis	06/09/2017	06/09/2017	02/08/2017	12/09/2017	26/09/2017	26/09/2017	15/11/2017	Please Select	
70	17/LO/0849	222165	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)	06/09/2017	06/09/2017	02/08/2017	12/09/2017	26/09/2017	26/09/2017	13/12/2017	Neither	The study did not recruited in the first 70 days due to tight eligibility criteria, particularly relating to HbA1c and Platelet levels. Four patients were screened during the screening period but 3 screen failed. One patient was deemed not eligible for this study due to NASH CRN classification in the opinion of the central reader being listed as F3 and not F4 this patient has been transferred and enrolled into the Stellar 3 study
71	15/LO/0609	171006	STEPPED WEDGE RANDOMISED TRIAL OF LAPAROSCOPIC VENTRAL MESH RECTOPEXY IN ADULTS WITH CHRONIC CONSTIPATION	24/07/2017	24/07/2017	15/06/2016	10/08/2017	07/09/2017	07/09/2017		Sponsor	Original delays were due to sponsor query's with the contract. A piece of equipment provided by the study centre for the initial diagnostic procedure, does not meet trust requirements for infection control. The research team have flagged this to the study centre and are waiting instructions before the team are able to recruit their first patient
72	16/LO/1589	200691	A PHASE 3, PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, MULTI-CENTER, STUDY OF THE EFFICACY AND SAFETY OF LANREOTIDE AUTOGEL/ DEPOT 120 MG PLUS BSC VS. PLACEBO PLUS BSC FOR TUMOR CONTROL IN SUBJECTS WITH WELL DIFFERENTIATED, METASTATIC AND/OR UNRESECTABLE TYPICAL OR ATYPICAL LUNG NEUROENDOCRINE TUMORS	03/05/2017	03/05/2017	07/12/2016	18/07/2017	18/07/2017	18/07/2017		Sponsor	Multiple contracting problems between the Trust PI, Pharmacy, GCP, MHRA and Sponsor caused initial delays. The research team have pre-screened 240 patients and not one has been suitable. There has only been 2 patients recruited in the UK since the study commenced
73	17/NE/0138	202975	Advanced clinical blood analysis; imaging flow cytometry for detection and differentiation of eosinophilia in multiple diseases of childhood	06/07/2017	06/07/2017	25/05/2017	10/07/2017	10/07/2017	10/07/2017	05/08/2017	Please Select	
74	16/EE/0065	192416	Survival Improvement with Cholecalciferol in Patients on Dialysis – The SIMPLIFIED Registry Trial	17/07/2017	20/07/2017	29/07/2016	04/08/2017	17/08/2017	23/08/2017	24/10/2017	Sponsor	Study was late getting approval from sponsor to open to recruitment because of sponsor internal Quality Checks. No patients were seen during the 70 day window
75	17/LO/0182	213821	A Prospective, Randomized, Multicenter Controlled Trial of CERAMENT™|G as Part of Surgical Repair of Open Diaphyseal Tibial Fractures	14/07/2017	14/07/2017	30/03/2017	09/08/2017	09/08/2017	09/08/2017		Neither	No eligible participants seen during the reported period because of the strict participant eligibility criteria

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76	17/SC/0229	225742	A modular, multi-arm, multi-part, first time in patient study to evaluate the safety and tolerability of OMO-1, alone and in combination with anti-cancer treatments, in patients with locally advanced, unresectable or metastatic solid malignancies	11/09/2017	27/09/2017	08/06/2017	03/10/2017	13/10/2017	19/10/2017	04/12/2017	Please select	
77	15/WA/0391	180498	A phase 2 study of the monocyte-targeted histone deacetylase inhibitor tefinostat (CHR-2845) in chronic myelomonocytic leukaemia (CMML	21/09/2017	21/09/2017	16/11/2016	26/09/2017	12/10/2017	12/10/2017		Sponsor	The study temporarily closed to recruitment after completely recruiting 'stage 1' of the trial. An IDMC was due to take place in November to assess the toxicity data prior to the trial re-opening recruitment for stage 2 of the study. The SIV was in January when recruitment re-opened. No patient has been identified to date
78	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
79	17/YH/0013	213247	A RandomizEd trial of ENtERal Glutamine to minimIZE thermal injury	17/07/2017	01/08/2017	27/04/2017	05/09/2017	12/10/2017	13/10/2017	21/02/2018	Sponsor	Sponsor contracting delays from the site being selected took 72 days. Since then we have been screening but no eligible patients have been admitted to the critical care unit within this time frame. We have extended our screening to the burns unit now to hopefully find our first patient
80	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	
81	17/YH/0120	208838	A pragmatic multi-centre randomised controlled non-inferiority, cost effectiveness trial comparing injections of collagenase into the cord to surgical correction in the treatment of moderate Dupuytren's Contracture in adult patients.	28/09/2017	28/09/2017	25/05/2017	02/09/2017	16/10/2017	16/10/2017	25/01/2018	Neither	The study has not met the 70 day target at this site because there have been no eligible participants seen during the reported period
82	16/SC/0200	202397	Proof-of-Concept Trial on Selective Removal of the Antiangiogenic Factor Soluble Fms-like Tyrosine Kinase-1 (sFlt-1) in Pregnant Women with Preeclampsia via Apheresis Utilizing the Flt-1 Adsorption Column	31/07/2017	04/08/2017	29/07/2016	14/09/2017	04/10/2017	04/10/2017		NHS Provider	Initial problems with the contract were due to the Trust identifying specific areas for storage of the device/machine to be used for the study. No eligible participant was been identified during the reported period. However, screening is carried out on a daily basis
83	15/EM/0323	76077	LCH- -IV -International Collaborative Treatme nt Protocol for Children and Adolescents with Langerhans Cell Histioc ytosis	25/09/2017	24/10/2017	19/07/2016	26/10/2017	30/10/2017	30/10/2017	01/11/2017	Please select	
84	16/LO/2141	200571	Biological Medicine for Diffuse Intrinsic Pontine Glioma (DIPG) Eradication (Biomede)	31/08/2017	31/08/2017	06/04/2017	15/08/2017	09/10/2017	09/10/2017	06/03/2018	Neither	Unable to recruit to 70 day target as no eligible patient with this rare childhood condition presented within that time frame

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85	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
86	17/LO/1139	209931	A multi-centre randomised, parallel group pilot clinical trial investigating the feasibility of a definitive trial of a permissive temperature strategy in critically ill children with known or suspected infection.	14/09/2017	14/09/2017	11/08/2017	29/09/2017	13/10/2017	13/10/2017	24/10/2017	Please select	
87	17/NE/0117	222778	A Phase 2b, Multicentre, Multinational, Placebo-controlled, Double-blind, Dose-finding Study in Adult Patients with Type I, III or IV Osteogenesis Imperfecta Treated with BPS804	29/09/2017	29/09/2017	25/08/2017	06/10/2017	16/10/2017	16/10/2017		Neither	Pre-screening genetic testing is taking at least 8 weeks as this is a rare disease. No patients have presented to date
88	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
89	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		Both	Sponsor was awaiting pharmacy confirmation that all processes were in place before allowing the study to start recruiting patients
90	17/SW/0220	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	
91	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
92	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

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93	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
94	15/NE/0013	159719	Radiation versus Observation following s urgical resection of Atypical Meningioma : a randomised controlled trial (The ROAM trial)	16/11/2017	16/11/2017	20/06/2016	16/11/2017	30/11/2017	30/11/2017		Sponsor	Delays were initially caused due to a substantial amendment with contract changes by the sponsor. An eligible patient was approached 21/07/2017 but the patient declined and did not consent
95	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
96	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		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
97	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	
98	15/LO/0485	138945	The prevention of pre-term birth in women who develop a short cervix. A multicentre randomised controlled trial to compare three treatments; cervical cerclage, cervical pessary and vaginal progesterone.	31/07/2017	08/08/2017	15/06/2017	05/10/2017	07/11/2017	09/11/2017		Sponsor	The study missed the 70 day benchmark because the contract was delayed by the sponsor failing to return the contract with the correct signatures in the proposed time limit. No patients have been recruited due to the strict eligibility criteria
99	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		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
100	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	
101	14/NW/0176	153733	A Prospective Randomized Controlled Study Evaluating the Safety and Efficacy of EVICEL® used for Suture-Line Sealing in Dura-Mater Closure during Paediatric Neurosurgical Cranial Procedures	17/10/2017	17/10/2017	16/05/2014	23/10/2017	09/11/2017	09/11/2017	08/01/2018	Neither	The first suitable patient was approached and agreed to participate but the surgery was cancelled on the day in December and theatre was not rearranged until January

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102	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	
103	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	
104	16/LO/2126	218039	A randomized trial comparing the ELUVIA™ 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	
105	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	
106	15/YH/0349	174392	An international phase II trial assessing tolerability and efficacy of sequential MethotrexateAracytinbased combination and RICE combination, followed by high-dose chemotherapy supported by autologous stem cell transplant, in patients with systemic B-cell lymphoma with central nervous system involvement at diagnosis or relapse (MARIETTA regimen)	19/05/2016	13/11/2017	15/06/2017	23/11/2017	07/12/2017	13/12/2017		Neither	The inclusion criteria for this study is very specific with requirements for CNS involvement with no previous high dose methotrexate based chemotherapy and/or brain irradiation. The Haematology Team have yet to identified any suitable trial subjects as this is a rare disease
107	16/LO/0592	179775	Phase III randomised trial of immunomo dulatory therapy in high risk solitary bon e plasmacytoma	30/10/2017	06/11/2017	09/08/2016	24/11/2017	01/12/2017	06/12/2017	22/01/2018	Neither	This study is a rare cancer with an incidence of approx. 1 per million population. During the 70 day target, we have had a single suitable patient referred to the department, consent/registration is not permitted until after the patient has completed a course of radiotherapy with a curative intent, hence we exceeded the 70 day target
108	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
109	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

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110	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	
111	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	
112	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	
113	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 eligiblity criteria during this period
114	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	
115	14/LO/0122	141557	A multi-centre, open-label, non-randomised, phase I dose escalation study of regorafenib (BAY 73-4506) in paediatric subjects with solid malignant tumours that are recurrent or refractory to standard therapy.	28/11/2017	28/11/2017	27/11/2017	08/12/2017	15/12/2017	15/12/2017	08/03/2018	Neither	This study is a rare disease and no eligible patient presented with the condition during the 70 day window
116	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 critieria and the teams inability to find suitable patients
117	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		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
118	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

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119	16/NE/0413	210215	Randomised, double blind, placebo controlled, multicentre study to evaluate the efficacy and safety of givinostat in ambulant patients with Duchenne Muscular Dystrophy.	20/07/2017	20/07/2017	13/03/2017	06/09/2017	10/08/2017	03/10/2017	10/01/2018	Neither	Recruitment was difficult due to the rare disease group needed. One patient was identified but did not want to begin study prior to Christmas due to intense schedule of visits
120	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	
121	16/SC/0147	183044	TriMaster: Randomised Double-Blind Crossover study of a DPP4 inhibitor, SGLT2 inhibitor and thiazolidinedione as third line therapy in patients with type 2 diabetes who have suboptimal glycaemic control on dual therapy with metformin and a sulphonylurea	16/06/2017	16/06/2017	07/07/2016	03/10/2017	13/10/2017	17/10/2017	13/02/2018	Sponsor	The study took 123 days to approve because of query problems between the sponsor and the trust with numerous items. Once the study was approved it was delayed further by the sponsors having a IMP supply issue between 23/10/17 and 21st December 2017. With the different departments involved in the set up process it was delayed awaiting responses from people in different departments
122	17/NE/0239	222301	Nasal Airway Obstruction Study	11/09/2017	14/09/2017	31/08/2017	02/11/2017	02/11/2017	02/11/2017	26/01/2018	Sponsor	Initial delays were caused by contracting signatures with the sponsor. Then the study required an substantial amendment for the use of Mometasone steroid spray for the study from the sponsor
123	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
124	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 theses 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
125	17/NE/0058	219540	A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors	20/09/2017	20/09/2017	13/04/2017	26/09/2017	16/10/2017	16/10/2017	04/12/2017	Neither	Patients were sought but none were eligible from the first cohort as the others were on hold.

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126	16/YH/0157	204585	PLATO - PersonaLising Anal cancer radioTherapy dOse - Incorporating Anal Cancer Trials (ACT) A CT3, ACT4 and ACT5	15/09/2017	15/09/2017	20/07/2016	27/10/2017	27/11/2017	27/11/2017	29/01/2018	Sponsor	Sponsor insisted that the Trust would sign the contract first. Hence the contract went back and forward between Trust and Sponsor before a resolution was compromised. The study was already past the benchmark before the study was approved by R&D
127	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
128	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	
129	17/NI/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	
130	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 particaipant was seen during the reporting period
131	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		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
132	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.
133	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 longor 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)
134	17/LO/1015	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

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135	14/LO/2137	164744	Anti-Influenza Hyperimmune Intravenous Immunoglobulin Clinical Outcome Study (INSIGHT 006:FLU-IVIG)	03/01/2018	03/01/2018	15/11/2016	03/01/2018	03/01/2018	03/01/2018	02/02/2018	Please select	
136	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		Please select	
137	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	
138	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		Please select	
139	17/NE/0325	227986	EMPOWER: EMesis in Pregnancy - Ondansetron With mEtoclopRamide.	11/12/2017	08/01/2018	30/11/2017	06/02/2018	06/02/2018	08/02/2018		Sponsor	The study is still awaiting green light from sponsor; Delays with the IMP manufacturing/packaging resulted in delays to the whole trial and issues with the eCRF
140	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	
141	17/SC/0345	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		Please select	
142	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		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
143	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		Please select	
144	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		Please select	

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145	17/EE/0335	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		Please select	
146	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		Please select	
147	18/WA/0053	235929	A passport for patients with non-cystic fibrosis bronchiectasis: a qualitative investigation of patients' beliefs and expectations	22/03/2018	22/03/2018	14/03/2018	23/03/2018	23/03/2018	23/03/2018		Please select	
148	14/NE/1200	164160	Airway Intervention Registry extension: Recurrent Respiratory Papillomatosis	01/03/2018	01/03/2018	01/03/2018	01/03/2018	01/03/2018	01/03/2018		Please select	
149	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		Please select	
150	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		Please select	
151	17/LO/1134	228166	PrEP Impact Trial: A Pragmatic Health Technology Assessment of PrEP and Implementation	28/02/2018	28/02/2018	03/08/2017	01/03/2018	01/03/2018	01/03/2018		Please select	
152	17/SW/0212	233406	Genomic Imaging in Neonatal Encephalopathy (GENIE) study	27/03/2018	27/03/2018	02/10/2017	27/03/2018	27/03/2018	27/03/2018		Please select	
153	18/HRA/1342	241136	Identification of the optimal role and clinical setting where a point of care test for Clostridium difficile test might lead to greatest benefit: a care pathway analysis	20/03/2018	20/03/2018	28/02/2018	22/01/2018	20/03/2018	20/03/2018		Please select	
154	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 sponor and finance to resolve
155	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	

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156	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	
157	17/LO/1267	218569	Critically ill children and young people: do national Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes and patient experience? The DEPICT study	27/02/2018	27/02/2018	03/10/2017	01/03/2018	01/03/2018	01/03/2018	04/03/2018	Please select	
158	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		Please select	
159	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 70 day benchmark
160	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
161	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 problems
162	17/NW/0247	222303	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc 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 one of 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