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	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
2	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	
3	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
4	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. Study has now been closed by sponsor
5	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	
6	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
7	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
8	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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9	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 implemented an amendment re-introducing further disease cohorts and consented a their first patient
10	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
11	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	
12	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	
13	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	
14	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	
15	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	
16	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

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17	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	
18	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
19	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 were identified while the study was open to recruitment and the sponsor decided to close the site early
20	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. The team extended their screening to the burns unit to find their first patient
21	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	
22	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
23	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	
24	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
25	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

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26	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	
27	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	16/05/2018	Neither	Pre-screening genetic testing is taking at least 8 weeks as this is a rare disease. No patients presented until May 2018
28	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
29	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
30	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	
31	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
32	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
33	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

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34	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
35	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
36	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	
37	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
38	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	
39	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
40	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	
41	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	
42	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	

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43	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	
44	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	01/06/2018	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 did not identify any suitable trial subjects within the reporting period as this is a rare disease
45	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
46	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
47	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	
48	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	
49	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	
50	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

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51	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	
52	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
53	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
54	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
55	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
56	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
57	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	
58	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
59	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

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60	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
61	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.
62	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 and also missed the 30 day deadline before the study was approved by R&D
63	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
64	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	
65	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	
66	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
67	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

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68	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.
69	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)
70	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
71	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	
72	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		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
73	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
74	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	
75	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

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76	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		Neither	This study has a particularly complex inclusion criteria and the final say sits with the sponsor. The team have identified one participant and if sponsor gives the OK screening will go ahead
77	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
78	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
79	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
80	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
81	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

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82	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 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
83	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
84	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
85	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	
86	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. The study was withdrawn by the sponsor and is now completed
87	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

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88	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	
89	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	
90	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	
91	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
92	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
93	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	
94	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
95	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
96	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

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97	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	
98	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	
99	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	
100	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
101	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
102	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	
103	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
104	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	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
105	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

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106	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
107	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
108	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		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
109	17/WM/0297	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
110	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
111	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
112	17/YH/0220	222317	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	

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113	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
114	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
115	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
116	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		Neither	The study has not recruited yet because the study focuses on a rare cancer type and has stringent inclusion and exclusion criteria
117	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	
118	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	
119	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	

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120	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	
121	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	
122	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	
123	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		Please select	
124	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		Please select	
125	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
126	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		Please select	
127	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		Please select	
128	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
129	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	

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130	18/NW/0105	239560	ELectrical COupling Information From The RhythmiaTM HDx Mapping System And DireCtSenseTM 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	
131	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	
132	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		Please select	
133	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		Please select	
134	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	
135	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		Please select	
136	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
137	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	

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138	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	
139	15/NE/0243	161536	Investigating a Self-Care Model for Patients with Prostate Cancer	29/05/2018	31/05/2018	19/01/2018	18/06/2018	18/06/2018	18/06/2018		Please select	
140	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		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
141	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		Please select	
142	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		Please select	
143	17/LO/0023	215490	MUK nine b: OPTIMUM. A phase II study evaluating multiple novel agentsoptimised 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		Please select	
144	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
145	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		Sponsor	Long contracting delays with the sponsor caused the study to be approved late
146	18/NE/0076	232845	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		Please select	
147	18/LO/0151	237090	Alpha Defensin use in Periprosthetic Joint Infection revision surgery	21/04/2018	05/06/2018	23/03/2018	05/06/2018	05/06/2018	05/06/2018		Please select	
148	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		Please select	

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149	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		Please select	
150	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		Please select	
151	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		Please select	
152	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		Please select	
153	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
154	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		Please select	
155	14/NE/1240	163350	AN OPEN-LABEL PHASE 1B STUDY OF PF 04449913 (GLASDEGIB) IN COMBINATION WITH AZACITIDINE IN PATIENTS WITH PREVIOUSLY UNTREATED HIGHER RISK MYELODYSPLASTIC SYNDROME, ACUTE MYELOID LEUKEMIA , OR CHRONIC MYELOMONOCYTIC LEUKEMIA	22/05/2018	22/05/2018	01/03/2018	28/05/2018	04/06/2018	04/06/2018		Please select	
156	17/NE/0231	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	
157	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	26/06/2018	NHS Provider	The study was unable to recruit within the time frame due to a number of factors including a lack of trained staff to deliver the laser treatment