| 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 | 18/YH/0358 | 242342 | A randomised controlled trial to establish the clinical and cost effectiveness of expectant management versus pre-operative imaging with Magnetic Resonance Cholangiopancreatography (MRCP) in patients with symptomatic gallstones undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones | 02/03/2020 | 02/10/2020 | 12/12/2018 | 02/10/2020 | 02/10/2020 | 06/10/2020 | 26/11/2020 | Please select | |
| 2 | 20/NE/0052 | 277285 | Elite Study | 17/09/2020 | 21/10/2020 | 15/04/2020 | 27/10/2020 | 27/10/2020 | 29/10/2020 | 08/12/2020 | Please select | |
| 3 | 20/NE/0189 | 280542 | Feasibility study for identification of patients at potential risk of silent aspiration in an acute stroke setting: a comparison of clinical swallow examination and cough reflex testing | 05/03/2020 | 30/10/2020 | 17/09/2020 | 30/10/2020 | 30/10/2020 | 30/10/2020 | 05/11/2020 | Please select | |
| 4 | 20/YH/0231 | 284781 | A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH DIABETIC MACULAR EDEMA | 02/10/2020 | 20/10/2020 | 10/09/2020 | 20/10/2020 | 20/10/2020 | 21/10/2020 | 29/10/2020 | Please select | |
| 5 | 19/EE/0362 | 272768 | A Randomised Multiple Centre Trial of Conservative versus Liberal Oxygenation Targets in Critically Ill Children (Oxy-PICU) | 15/10/2020 | 15/10/2020 | 23/12/2019 | 20/10/2020 | 21/10/2020 | 21/10/2020 | 29/10/2020 | Please select | |
| 6 | 20/HRA/4788 | 288786 | A Phase 2/3, Randomized, Placebo-Controlled, Double-Blind Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MK-4482 in Non-Hospitalized Adults with COVID-19 | 12/10/2020 | 19/10/2020 | 05/10/2020 | 20/10/2020 | 20/10/2020 | 20/10/2020 | 29/10/2020 | Please select | |
| 7 | 19/LO/1652 | 271917 | Phase 3, open-label, single arm study to evaluate efficacy and safety of FIX gene transfer with PF-06838435 (rAAV-Spark100-hFIX-Padua) in adult male participants with moderately severe to severe hemophilia B (FIX:C≤2%) (BeneGene-2) | 29/10/2020 | 30/10/2020 | 28/01/2020 | 09/11/2020 | 09/11/2020 | 10/11/2020 | | Neither | Newcastle was the infusion site for a patient being recruited at Glasgow. The reason for delay of a patient entering the study, was due to the escalating COVID pandemic and in the intervening time things have improved and Glasgow have been able to set up to perform the infusion themselves |
| 8 | 20/SC/0027 | 271232 | A Long-term Follow-up Study of Patients in the Clinical Trials for Spinal Muscular Atrophy Receiving AVXS-101 | 30/03/2020 | 13/10/2020 | 06/04/2020 | 11/11/2020 | 17/11/2020 | 17/11/2020 | | Sponsor | Delays to recruitment have been caused by the sponsor confirming the finer details of an amendment |
| 9 | 20/NW/0310 | 267092 | A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease (CVD). | 14/11/2019 | 12/10/2020 | 24/09/2020 | 04/11/2020 | 04/11/2020 | 04/11/2020 | 04/12/2020 | Please select | |

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| 10 | 19/LO/0213 | 256261 | A Phase 1 Trial of the combination of PS101-Mediated Acoustic Cluster Therapy (ACT) with Chemotherapy for the Treatment of Liver Metastasis in Patients with Solid Tumours with an Expansion Cohort in Metastatic Colorectal and Pancreatic Cancer | 16/10/2020 | 20/10/2020 | 07/05/2019 | 22/10/2020 | 22/10/2020 | 03/11/2020 | | Neither | This study is not formally open at Newcastle, as COVID has delayed the Royal Marsden NHS finishing the first bit of dose ending. We are still waiting for the SIV and delivery of the USS equipment |
| 11 | 20/YH/0317 | 288552 | A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older | 17/09/2020 | 18/11/2020 | 10/11/2020 | 19/11/2020 | 20/11/2020 | 20/11/2020 | 01/12/2020 | Please select | |
| 12 | 19/NE/0310 | 263546 | A Phase IIb double-blind, randomised, placebo-controlled, multi-centre, confirmative three-way cross-over study on cognitive function with two doses of KH176 in subjects with a genetically confirmed mitochondrial DNA tRNALeu(UUR) m.3243A>G mutation | 26/10/2020 | 26/10/2020 | 31/03/2020 | 18/12/2020 | 30/12/2020 | 30/12/2020 | 17/03/2021 | Both | Initial delays were caused by contacting problems within the NHS and Sponsor provider. Considerable delays to recruitment were due to facilitation of tests at site and then prolonged wait times between screening and return of invetigational results to validate proceeding to dosing |
| 13 | 19/LO/1926 | 274398 | A Phase 1/2 Open Label Study to Assess the Safety and Efficacy of UCB6114 Administered Intravenously to Participants with Advanced Solid Tumors | 11/02/2020 | 17/11/2020 | 19/02/2020 | 08/12/2020 | 09/12/2020 | 09/12/2020 | 02/03/2021 | Neither | As this study is a phase I dose finding study and first allocated slots on a cohort were not until the site opened. The cohorts were slow for the first 'sentinel' patient and it was not Newcastle's turn to treat first, causing delays to the first recruit at this site |
| 14 | 20/LO/0731 | 279972 | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Prurigo Nodularis | 13/05/2020 | 25/11/2020 | 25/06/2020 | 16/12/2020 | 16/12/2020 | 17/12/2020 | 30/06/2021 | NHS Provider | Delays to recruitment has been caused by the loss of a research nurse and the study needs two. A nurse has been employed and will start with the study team in the near future |
| 15 | 20/SC/0031 | 275229 | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis | 27/11/2020 | 27/11/2020 | 26/06/2020 | 16/12/2020 | 17/12/2020 | 17/12/2020 | | NHS Provider | Staff capacity issues caused delays in receiving the sponsor's green light to commence recruitment. Global rectuitment ended prior to staff capacity issues were resolved at this site |
| 16 | 20/EE/0118 | 283014 | COG-UK HOCI study | 09/09/2020 | 07/12/2020 | 15/06/2020 | 07/12/2020 | 07/12/2020 | 07/12/2020 | 15/12/2020 | Please select | |
| 17 | 20/EM/0142 | 282923 | Phase IIb Multi-Center, Randomised, Partial-Blind Parallel Cohort Study to Assess the Efficacy and Safety of Treatment with GSK3228836 in Participants with Chronic Hepatitis B Virus (B-Clear) | 15/09/2020 | 25/11/2020 | 16/07/2020 | 10/12/2020 | 14/12/2020 | 14/12/2020 | 21/01/2021 | Please select | |
| 18 | 18/WM/0270 | 239150 | TWIST – Trial of Wound drain In Surgical site infection in kidney Transplant | 15/10/2020 | 15/10/2020 | 15/11/2018 | 24/11/2020 | 01/12/2020 | 01/12/2020 | 06/01/2021 | Sponsor | Contracting delays within sponsor company |
| 19 | 20/WM/0054 | 264593 | CRAFFT – Children's Radius - Acute Fracture Fixation Trial: A multi-centre prospective randomised non-inferiority trial of surgical reduction versus non-surgical casting for displaced distal radius fractures in children. | 16/10/2020 | 16/12/2020 | 16/04/2020 | 18/12/2020 | 18/12/2020 | 18/12/2020 | 20/03/2021 | Neither | Recruitment was delayed due to COVID and fewer than usual children's fractures have been seen this year due to children not playing out due to the pandemic |

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| 20 | 20/NE/0032 | 273692 | A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF ATEZOLIZUMAB PLUS CARBOPLATIN AND ETOPOSIDE WITH OR WITHOUT TIRAGOLUMAB (ANTI-TIGIT ANTIBODY) IN PATIENTS WITH UNTREATED EXTENSIVE-STAGE SMALL CELL LUNG CANCER | 07/09/2020 | 01/10/2020 | 28/07/2020 | 09/10/2020 | 09/10/2020 | 09/10/2020 | | Neither | A change in population due to COVID 19 caused delays to recruitment. The site closed to recruitment in March 2021 and failed to recruit any patients. Due to coronavirus the patients were presenting with more advanced disease and poorer performance status than would be eligible for the study. |
| 21 | 18/SW/0130 | 246372 | Prospective Evaluation of Thin-strut Biodegradable Polymer-coated Supraflex Sirolimus-Eluting Stents in an All-comers Patient Population (S-FLEX UK-II) | 16/05/2018 | 08/12/2020 | 29/06/2018 | 11/01/2021 | 12/01/2021 | 13/01/2021 | 26/01/2021 | Please select | |
| 22 | 19/NW/0571 | 261307 | An adaptive, Phase 2 randomised double-blind, placebo-controlled multi-centre study to evaluate the safety and efficacy of multiple LOU064 doses in patients with moderate to severe Sjögrens syndrome (LOUiSSe) | 24/09/2019 | 16/12/2020 | 06/01/2020 | 18/12/2020 | 18/12/2020 | 11/01/2021 | | NHS Provider | There was delays with the pharmacy green light and the Part 1 cohort needed to have completed recruitment before Newcastle were able to start with this study cohort. |
| 23 | 19/LO/0712 | 257246 | IP4- CHRONOS: Comparative Health Research Outcomes of NOvel Surgery in Prostate Cancer | 08/01/2021 | 08/01/2021 | 07/08/2019 | 25/01/2021 | 25/01/2021 | 25/01/2021 | 17/05/2021 | Neither | This is a difficult study to recruit to as two of the three treatments are available outside the trial and patients have quite often had strong opinions about their treatment |
| 24 | 20/SC/0223 | 279425 | Long-term Safety and Tolerability Study of Linerixibat for the Treatment of Cholestatic Pruritus in Participants with Primary Biliary Cholangitis | 14/12/2020 | 14/12/2020 | 08/07/2020 | 15/01/2021 | 25/01/2021 | 25/01/2021 | 19/03/2021 | Neither | Set up was initially delayed due to COVID-19 however, once Newcastle received the green light on 25/02/2021 study information was sent out to patients. As soon as consent was received staff booked their screening and Newcastle recruited the first 2 patients in the UK on 19/03/2021 |
| 25 | 20/NW/0312 | 284188 | A Registry-based, Randomised, Double-blind, Placebo-Controlled Cardiovascular Outcomes Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Heart Failure or Cardiovascular Death in Patients without Diabetes with Acute Myocardial Infarction at Increased Risk for Subsequent Development of Heart Failure | 07/09/2020 | 08/12/2020 | 23/07/2020 | 21/01/2021 | 21/01/2021 | 25/01/2021 | 10/06/2021 | Sponsor | Initial delays were caused by contracting delays with the sponsor.The research team are also waiting for IP shipment. Once the IP has been acknowledged in IWRS the sponsor will activate Newcastle to begin recruitment |
| 26 | 20/NW/0383 | 287807 | A Phase 3 Randomized, Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Remdesivir (GS-5734™) Treatment of COVID-19 in an Outpatient Setting | 22/12/2020 | 22/12/2020 | 23/10/2020 | 22/01/2021 | 22/01/2021 | 25/01/2021 | | Sponsor | This COVID-19 Study was discontinued by sponsor in light of recent advances, the primary unmet need for patients outside of the hospital setting is for convenient, effective therapies that can be easily administered at home. |
| 27 | 20/SC/0303 | 1003379 | A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Participants with a diagnosis of Chronic Obstructive Pulmonary Disease and a history of Chronic Bronchitis with a History of Moderate or Severe Acute Exacerbations Receiving Standard of Care Maintenance Therapy | 22/12/2020 | 22/12/2020 | 09/10/2020 | 21/01/2021 | 22/01/2021 | 22/01/2021 | 21/07/2021 | Both | Initial delays were caused by post SIV set up issues with regards to study equipment. Then staff shortages have also impacted on the studies ability to recruit patients during the relevant period |

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| 28 | 20/WM/0220 | 285844 | A Phase Ib/IIa, randomized, double-blind placebo-controlled, multicenter adaptive design clinical trial to evaluate the immune signature of the treatment with the Imotope™ IMCY-0098 and its effect on the preservation of beta-cell function in young adult and adolescent patients with a recent onset Type 1 diabetes | 30/11/2020 | 30/11/2020 | 11/09/2020 | 08/01/2021 | 08/01/2021 | 25/01/2021 | 11/03/2021 | Neither | This is a trial of a very bespoke immunotherapy for people with newly diagnosed Type 1 diabetes age 18-45. This means finding eligible subjects is a challenge. People are diagnosed with Type 1 diabetes - about 3 patients per month. The eligibility then requires them to have a specific antibody profile and the correct genetic type. |
| 29 | 20/NE/0250 | 284888 | A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination with Ruxolitinib Versus Best Available Therapy in Subjects with Relapsed/Refractory Myelofibrosis | 30/10/2020 | 09/12/2020 | 27/11/2020 | 21/12/2020 | 21/12/2020 | 07/01/2021 | | Neither | This study has a strict inclusion criteria as the main requirement is for platelets above 100. No patient have been identified |
| 30 | 20/HRA/5205 | 289098 | A PHASE I/II RANDOMIZED, TWO PARTS, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND IMMUNOGENICITY OF AN INACTIVATED, ADJUVANTED SARS-COV-2 VIRUS VACCINE CANDIDATE (VLA2001), AGAINST COVID-19 IN HEALTHY INDIVIDUALS | 21/12/2020 | 21/12/2020 | 16/12/2020 | 02/01/2021 | 04/01/2021 | 04/01/2021 | 06/01/2021 | Please select | |
| 31 | 20/NE/0253 | 288479 | COVID-NURSE: evaluation of the effects of a COVID-specific fundamental nursing care protocol compared to care as usual on experience of care for non-invasively ventilated patients in hospital with the SARS-CoV-2 virus: a randomised controlled trial. | 05/01/2021 | 11/01/2021 | 11/11/2020 | 12/01/2021 | 12/01/2021 | 13/01/2021 | 07/04/2021 | Sponsor | The remote SIV did not happen until 3rd March 2021. The study opened to recruitment on 22nd March and the team then actively looked for recruits |
| 32 | 20/HRA/5234 | 290965 | A randomised, double-blind, placebo-controlled, Phase III trial to determine the efficacy and safety of inhaled SNG001 for the treatment of patients hospitalised due to moderate COVID-19 | 14/01/2021 | 25/01/2021 | 09/11/2020 | 29/01/2021 | 29/01/2021 | 29/01/2021 | 15/02/2021 | Please select | |
| 33 | 19/SC/0094 | 240646 | Intravenous immunoglobulin and intravenous methylprednisolone as optimal induction treatment in CIDP | 23/11/2020 | 23/11/2020 | 16/05/2019 | 05/02/2021 | 08/02/2021 | 08/02/2021 | | Sponsor | Intial delays were caused by sponsor query resolutions. This study deals with rare patients and none have been identified that meet the strict eligibility criteria' |
| 34 | 19/LO/1892 | 272434 | A multicenter, randomized, active-controlled, double-blind, double-dummy, parallel group clinical trial, investigating the efficacy, safety, and tolerability of continuous subcutaneous ND0612 infusion in comparison to oral IR-LD/CD in subjects with Parkinson's disease experiencing motor fluctuations (BouNDless) | 13/09/2019 | 21/01/2021 | 21/01/2020 | 05/02/2021 | 09/02/2021 | 09/02/2021 | 21/06/2021 | Sponsor | Delayed by sponsor because of freezer and used IMP vials and their storage. No patient consented until June 2021 |

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| 35 | 19/NW/0135 | 252254 | An International Randomised Clinical Trial of Therapeutic Interventions with the Potential to Improve Outcome in Adults with Acute Myeloid Leukaemia and High Risk Myelodysplasia Undergoing Allogeneic Stem Cell Transplantation | 23/03/2020 | 14/01/2021 | 17/05/2019 | 20/01/2021 | 23/02/2021 | 24/02/2021 | | Neither | To be eligible for this trial patients have to have a specific diagnosis and donor combination. The relatively small number of allogeneic transplants Newcastle perform means there will always be peaks and troughs of eligible patients. The first person approached declined the trial. |
| 36 | 20/NW/0177 | 1003027 | Phase 3b Open-Label, Multicenter, Safety Study of BIIB037 (aducanumab) in Subjects with Alzheimer's disease Who Had Previously Participated in the Aducanumab Studies 221AD103, 221AD301, 221AD302 and 221AD205. | 20/04/2020 | 20/01/2021 | 12/06/2020 | 05/02/2021 | 05/02/2021 | 05/02/2021 | 15/04/2021 | Neither | This study was only available to participants who had taken part in a previous study. Delays to recruitment were caused to their availability, medical staff availability and getting all in house documents/approvals in place |
| 37 | 20/EM/0089 | 278775 | A PHASE IB, OPEN-LABEL, NON-RANDOMIZED, MULTICENTER STUDY EVALUATING THE SAFETY, PHARMACOKINETICS, AND EFFICACY OF MOSUNETUZUMAB IN COMBINATION WITH LENALIDOMIDE OR RO7082859 IN COMBINATION WITH LENALIDOMIDE OR RO7082859 IN COMBINATION WITH OBINUTUZUMAB PLUS LENALIDOMIDE IN PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA | 10/08/2020 | 22/01/2021 | 30/07/2020 | 29/01/2021 | 29/01/2021 | 01/02/2021 | | Sponsor | The trial received green light from pharmacy on the 5th Feb and on the 30th March the team were told all screening slots had been filled and the study had moved to waiting list. Since then the team have been waiting on a new protocol amendment which adds 75 patient slots |
| 38 | 20/NW/0300 | 285728 | A Phase 3, randomized, double-blind, efficacy and safety study comparing SAR442168 to placebo in participants with nonrelapsing secondary progressive multiple sclerosis (HERCULES) | 18/08/2020 | 16/12/2020 | 15/09/2020 | 04/02/2021 | 04/02/2021 | 05/02/2021 | 24/09/2021 | Neither | Initial set up was delayed due to COVID-19. This study has not yet recruited as it has extensive inclusion/exclusion criteria. Three patients have been identified but two have declined participation after reading PIS as they feel the study is too intensive |
| 39 | 20/LO/0031 | 266400 | Perinatal and 2 year neurodevelopmental outcome in late preterm fetal compromise: the TRUFFLE 2 Randomised Trial | 14/09/2020 | 18/01/2021 | 04/02/2020 | 08/02/2021 | 03/02/2021 | 09/02/2021 | 25/08/2021 | Neither | No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population |
| 40 | 20/EM/0173 | 281569 | Tapering of Biologics in Inflammatory Arthritis Patients in Remission | 16/10/2020 | 10/11/2020 | 31/07/2020 | 19/02/2021 | 25/02/2021 | 25/02/2021 | | Sponsor | Sponsor contracting delays due to financial aspects. This is a pilot study and the recruitment rate is actually one of the outcomes. It has been flagged with consultant colleagues who would need to identify most patients, but we have had no referrals. General business will undoubtedly play a part, but the team are stepping up the recruitment strategy with posters in offices at telephone clinics and pre-screening clinic lists |
| 41 | 20/LO/1128 | 288114 | A Phase 3, Multicenter, Randomized, Efficacy Assessor-Blinded Study of Risankizumab Compared to Ustekinumab for the Treatment of Adult Subjects With Moderate to Severe Crohn's Disease Who Have Failed Anti-TNF therapy | 05/02/2021 | 05/02/2021 | 03/12/2020 | 16/02/2021 | 17/02/2021 | 17/02/2021 | 21/04/2021 | Neither | No eligible patients were identified |

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| 42 | 20/NE/0172 | 275551 | A phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of PF-06939926 for the treatment of Duchenne muscular dystrophy | 16/11/2020 | 29/01/2021 | 15/10/2020 | 04/02/2021 | 04/02/2021 | 04/02/2021 | 22/03/2021 | Please select | |
| 43 | 19/LO/0911 | 263607 | A Phase 1/2 trial on the safety, tolerability, pharmacokinetics, pharmacodynamics and exploratory efficacy of DYN101 in patients ≥ 16 years of age with centronuclear myopathies caused by mutations in DNM2 or MTM1. | 26/02/2021 | 26/02/2021 | 08/08/2019 | 24/03/2021 | 25/03/2021 | 25/03/2021 | | NHS Provider | Recruitment has been delayed due to pharmacy green light only been given for this study on the 16th July, 2021. Participants have been contacted and screenings is being planned |
| 44 | 20/SC/0007 | 264068 | A PHASE I/II, MULTICENTER, OPEN-LABEL, MULTI-ARM STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PRELIMINARY ACTIVITY OF IDASANUTLIN IN COMBINATION WITH EITHER CHEMOTHERAPY OR VENETOCLAX IN THE TREATMENT OF PEDIATRIC AND YOUNG ADULT PATIENTS WITH RELAPSED/REFRACTORY ACUTE LEUKEMIAS OR SOLID TUMORS | 11/02/2021 | 11/02/2021 | 21/02/2020 | 23/03/2021 | 23/03/2021 | 23/03/2021 | 12/07/2021 | Sponsor | This study deals with very rare Patients and the treatment cohort is paused pending a decision by the dose review. The team have not been able to screen however, they expect to open for recruitment soon and the team have been waiting to see a patient from Dublin |
| 45 | 19/YH/0379 | 251669 | A multi-stage randomised trial of durvalumab (Medi4736) with chemoradiotherapy with 5-fluorouracil and mitomycin C in patients with muscle-invasive bladder cancer | 11/03/2020 | 28/01/2021 | 07/02/2020 | 03/03/2021 | 05/03/2021 | 11/03/2021 | 16/07/2021 | Neither | One eligible patient was approached who declined trial entry. The team did not find another eligible patient until July 2021 |
| 46 | 20/YH/0178 | 283168 | A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with Teriflunomide, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety. | 11/06/2020 | 26/02/2021 | 29/07/2020 | 18/03/2021 | 19/03/2021 | 19/03/2021 | | Neither | This study is looking for a very niche group of patients which was highlighted to the sponsor throughout set-up. Although, the team were confident they would recruit the study closed nationally before they were able to identify a patient |
| 47 | 20/SC/0288 | 281708 | FORTIS: A Phase 1/2, Open-Label, Ascending-Dose Clinical Study to Evaluate the Safety and Preliminary Efficacy of AT845, an AAV8-Delivered Gene Transfer Therapy in Patients with Late Onset Pompe Disease | 04/09/2020 | 05/03/2021 | 15/01/2021 | 19/03/2021 | 23/03/2021 | 23/03/2021 | 21/07/2021 | Sponsor | Following confirmation of C&C the sponsor notified Newcastle of an amendment which had to be locally approved before they would issue green light. The team weren't able to proceed with study activation based on the approved version of the protocol that was in place when C&C was granted. The amendment was approved on 2nd June, and the team received sponsor green light on 8th June |
| 48 | 18/LO/0045 | 233362 | A PHASE Ib/II, OPEN-LABEL, MULTICENTER, RANDOMIZED UMBRELLA STUDY EVALUATING THE EFFICACY AND SAFETY OF MULTIPLE IMMUNOTHERAPY-BASED TREATMENT COMBINATIONS IN PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (MORPHEUS-LUNG) | 08/09/2020 | 12/02/2021 | 08/02/2018 | 25/03/2021 | 30/03/2021 | 30/03/2021 | 07/05/2021 | Sponsor | Contracting delays with sponsor company caused initial delays and no patient was seen who fitted the eligibility criteria |

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| 49 | 20/YH/0280 | 282001 | A platform study of DNA damage response inhibitors in combination with conventional radiotherapy in non small cell lung cancer | 27/10/2020 | 25/02/2021 | 06/11/2020 | 12/03/2021 | 16/03/2021 | 17/03/2021 | 15/06/2021 | Neither | No suitable patients were identified until June due the strict eligibility criteria |
| 50 | 20/WA/0121 | 276396 | British Heart Foundation Randomised Clinical Trial of Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI) | 11/11/2020 | 05/02/2021 | 20/05/2020 | 09/03/2021 | 09/03/2021 | 11/03/2021 | | NHS Provider | The study cannot recruit until 10 patients (not participants) have received the device. As they are not part of the study and will be used as practice for the PI/Sub I's we are waiting for the PI to create an information sheet for these people before the team can start the study |
| 51 | 20/LO/1234 | 290834 | A randomized controlled trial to compare the safety and efficacy of sirolimus-eluting biodegradable polymer ultra-thin stent (SUPRAFLEX™ Cruz) and everolimus-eluting biodegradable polymer stent (SYNERGY™) in treatment for three-vessel coronary artery disease: Multivessel TALENT. | 16/11/2020 | 22/02/2021 | 12/02/2021 | 25/03/2021 | 25/03/2021 | 25/03/2021 | 11/05/2021 | Neither | No eligible patients were identified |
| 52 | 19/LO/1866 | 270431 | PlasmaLyte Usage and assessment of kidney Transplant Outcomes in children: the PLUTO trial | 12/11/2020 | 17/12/2020 | 22/12/2019 | 19/01/2021 | 16/03/2021 | 16/03/2021 | | Neither | Set up was suspended initially due to COVID-19. The team did approach the first potential recruit some time ago, however the family unfortunately declined. This was reported back to the trial team. The next potential kidney transplant in a paediatric patient happened on 12/8 and the family and the family declined to take part. Potential recruits are being screened |
| 53 | 20/WA/0028 | 272436 | Post-Market Registry in Europe for the Use of CardioCel®, CardioCel® Neo and CardioCel® 3D | 04/12/2020 | 29/01/2021 | 17/03/2020 | 12/03/2021 | 16/03/2021 | 17/03/2021 | 12/04/2021 | Sponsor | Contracting delays with sponsor company. The study opened on 17th March 2021 and recruited their first patient 26 days later. |
| 54 | 20/EM/0284 | 288568 | A Phase IIb Multi-Center, Randomised, Open Label Study to Assess the Efficacy and Safety of Sequential Treatment with GSK3228836 followed by Pegylated Interferon Alpha 2a in Participants with Chronic Hepatitis B Virus (B-Together) | 30/12/2020 | 26/02/2021 | 22/12/2020 | 15/03/2021 | 17/03/2021 | 17/03/2021 | 28/04/2021 | Please select | |
| 55 | 18/LO/2033 | 252294 | When to Induce Labour to Limit risk in pregnancy hypertension – a multicentre, randomised controlled trial | 11/01/2021 | 23/02/2021 | 10/01/2019 | 08/03/2021 | 08/03/2021 | 11/03/2021 | | Neither | No eligible participants seen during the reported period because of the strict participant eligibility criteria due to the small patient population |
| 56 | 20/EE/0239 | 281697 | A Prospective, Multicenter, Long-Term Study to Assess the Safety and Efficacy of Nemolizumab (CD14152) in Subjects with Prurigo Nodularis | 12/01/2021 | 05/03/2021 | 29/01/2021 | 15/03/2021 | 16/03/2021 | 17/03/2021 | 03/06/2021 | Neither | Patients sought but no eligible patients identified |
| 57 | 20/NS/0128 | 276718 | Clinical evaluation of an automated language transcription and analysis app to assist speech and language therapists with clinical decision making in the evaluation of developmental language disorders | 12/01/2021 | 22/01/2021 | 08/01/2021 | 03/03/2021 | 12/03/2021 | 12/03/2021 | 27/04/2021 | NHS Provider | Local Capacity and Capability review delays. Once this was resolved and the study opened the team sought eligible patients |
| 58 | 20/WA/0203 | 281292 | POLARx Cardiac Cryoablation system Post Market Clinical Follow-up study | 02/02/2021 | 18/03/2021 | 10/08/2020 | 26/03/2021 | 29/03/2021 | 29/03/2021 | 14/04/2021 | Please select | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 59 | 20/NE/0178 | 269661 | EXercise to Prevent frailty and Loss Of independence in insulin treated older people with DiabetEs: The EXPLODE Trial | 04/06/2018 | 11/11/2020 | 14/08/2020 | 18/02/2021 | 25/02/2021 | 25/02/2021 | | Neither | This study was delayed due to COVID-19 restrictions impacting on study timelines and staff availability. Recruitment has been difficult due to the COVID impact and running a trial virtually rather than face to face clinics at the Diabetes Centre, making assessment of suitability very slow |
| 60 | 19/LO/0236 | 230338 | The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial - The EFFORT Trial | 19/09/2019 | 02/10/2020 | 05/07/2019 | 02/02/2021 | 03/02/2021 | 03/02/2021 | 13/04/2021 | Both | Initial delays were caused by sponsor and trust over contracting problems. No patients were seen who was suitable for the study until April 2021 |
| 61 | 20/LO/0676 | 273137 | Evaluation of Efficacy, Safety and Tolerability of NGM282 (Aldafermin) in a Phase 2b, Randomized, Double-blind, Placebo-controlled, Multi-center Study in Subjects with Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (ALPINE 4) | 07/05/2020 | 10/12/2020 | 13/07/2020 | 23/02/2021 | 22/02/2021 | 25/02/2021 | | Sponsor | Initial delays were caused by contracting delays with the sponsor. This study deals with a rare disease and has a strict inclusion criteria. The company announced that the drug did not work on less severe disease (F2-3) in a press release. Newcastle have delayed recruiting into this study until we were given sufficient information by the sponsor to determine if we wished to recruit our patients into the F4 study |
| 62 | 20/LO/1107 | 258344 | A pilot study to compare static night time Ankle Foot Orthosis (AFO) with Contracture Control Device (CCD) in the management of ankle contractures in ambulant boys with Duchenne Muscular Dystrophy (DMD). | 01/04/2021 | 01/04/2021 | 01/03/2021 | 20/04/2021 | 21/04/2021 | 21/04/2021 | 06/05/2021 | Please select | |
| 63 | 19/WM/0364 | 257918 | Letrozole or Clomifene, with or without metformin, for ovulation induction in women with polycystic ovary syndrome: a 2x2 factorial design randomised trial (The LOCI trial) | 23/02/2021 | 23/02/2021 | 09/06/2020 | 14/04/2021 | 21/04/2021 | 21/04/2021 | 10/06/2021 | Both | Delays intially were because of NHS Finance and sponsor answering finance queries. Other delays were caused by confirmation from sponsor for Green Light to recruit patients |
| 64 | 20/LO/0181 | 275690 | A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PVd) or Daratumumab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma | 26/02/2021 | 22/03/2021 | 02/06/2020 | 26/04/2021 | 26/04/2021 | 26/04/2021 | 08/06/2021 | Neither | No eligible patients were seen initially |
| 65 | 19/LO/1381 | 257176 | A Phase 4, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to<br>Evaluate the Efficacy and Safety of Erenumab in Adults With Chronic Migraine and Medication Overuse Headache | 05/05/2020 | 14/01/2021 | 29/10/2019 | 20/04/2021 | 20/04/2021 | 21/04/2021 | 11/06/2021 | Sponsor | Initial delays were caused by sponsor protocol amenedments. No eligible patient was seen until June 2021 |
| 66 | 20/NE/0264 | 286020 | Post-Stroke rapid assessment of Cardiac arrhythmia evaluation- The Pace Study | 23/02/2021 | 23/02/2021 | 10/02/2021 | 08/04/2021 | 08/04/2021 | 08/04/2021 | 21/04/2021 | Both | Local capacity and capability reviews were not completed in time |

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| 67 | 20/LO/1021 | 283786 | Randomised, double-blind, placebo-controlled, clinical study to evaluate the effect of opicapone 50 mg on Parkinson's disease patients with motor fluctuations and associated pain | 16/11/2020 | 04/03/2021 | 16/10/2020 | 01/04/2021 | 08/04/2021 | 08/04/2021 | | NHS Provider | Due to Urgent public health studies that take priority at Newcastle the pharmacy team were unable to provide their greenlight until 30/06/2021. No patient has been identified who meets the eligibility criteria |
| 68 | 20/NE/0014 | 272055 | Multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIG) and aspirin, versus IVIG and aspirin for prevention of coronary artery aneurysms in Kawasaki disease<br>(KD-CAAP: Kawasaki Disease Coronary Artery Aneurysm Prevention trial) | 16/11/2020 | 26/02/2021 | 18/02/2020 | 30/04/2021 | 30/04/2021 | 30/04/2021 | | Both | Contracting delays between both parties meant the study was not granted approval in time. The KD-CAAP study has not yet been given the Green Light by sponsor. This study is researching a rare condition in the paediatric population. |
| 69 | 20/SC/0433 | 282917 | Wrist Injury Strengthening Exercise: a randomised multicentre feasibility study of resistance exercise versus usual care for optimising function after distal radius fracture in adults aged 50 years or over | 24/02/2021 | 24/02/2021 | 05/01/2021 | 26/04/2021 | 26/04/2021 | 26/04/2021 | 12/08/2021 | Sponsor | Initial delays were caused by sponsor querying the protocol amendments. The reason this study was late to recruit is due to mainly logistical issues. There have been changes to clinic times due to COVID-19 and we have not always had available staff to cover. There was initially no eligible patients presented |
| 70 | 20/WA/0266 | 285192 | Prospective observational cohort study: To assess the utility of bio-degradable bile duct stent in the drainage of bile duct. | 01/03/2021 | 01/03/2021 | 26/10/2020 | 20/04/2021 | 22/04/2021 | 22/04/2021 | 03/08/2021 | Sponsor | Initial delays were caused by sponsor querying the protocol amendments. Delays have also been caused because the indications for the use of the stents used in this study is limited. Identifying patients has been slow especially with COVID screening criteria for patients |
| 71 | 20/SC/0334 | 287932 | A Multicentre, Adaptive, Randomised, Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalised Patients with COVID-19<br><br>Short Title: Therapeutics for Inpatients with COVID-19 (TICO)<br><br>INSIGHT Protocol Number: 014 / ACTIV-3 | 12/03/2021 | 12/03/2021 | 30/09/2020 | 07/04/2021 | 13/04/2021 | 13/04/2021 | 06/05/2021 | Please select | |
| 72 | 21/SC/0119 | 297443 | A single-blind, randomised, phase II UK multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules – Stage 2 | 24/03/2021 | 13/04/2021 | 12/04/2021 | 15/04/2021 | 16/04/2021 | 16/04/2021 | 20/04/2021 | Please select | |
| 73 | 19/NE/0145 | 254931 | FaR-RMS: An overarching study for children and adults with Frontline and Relapsed RhabdoMyoSarcoma | 15/05/2019 | 19/03/2021 | 22/07/2019 | 12/05/2021 | 17/05/2021 | 17/05/2021 | 26/05/2021 | Both | Contracting delays with costs caused the study to be delayed with approval |
| 74 | 19/LO/0288 | 235544 | A Randomised Placebo-Controlled Trial of Escitalopram and Nortriptyline with Standard Psychological Care for Depression in Parkinson's Disease | 16/09/2019 | 23/02/2021 | 13/11/2019 | 18/05/2021 | 20/05/2021 | 20/05/2021 | 24/06/2021 | Both | Delays were caused by contracting problems around the data sharing agreement alongside the standard contract |

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| 75 | 20/EM/0003 | 269023 | Multicentre, open-label, randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress. | 08/01/2020 | 24/03/2021 | 14/02/2020 | 06/05/2021 | 07/05/2021 | 07/05/2021 | 06/08/2021 | Both | Initial delays were caused by the local capacity and capability review not being completed in time. Subsequent delays have been caused by a clarification and change of routine practice was needed regards to the saturation limits in the study. The registered nurse and PI also needing to self isolate which has delayed in the recruitment of patients to the study |
| 76 | 21/SS/0013 | 271797 | Pain Relief in Major Amputation (PRIMA): A randomised clinical trial comparing pre-incision 'single-shot' nerve block and continuous peri-neural catheter for patients undergoing a major lower limb amputation | 30/04/2021 | 13/05/2021 | 15/03/2021 | 13/05/2021 | 14/05/2021 | 14/05/2021 | 12/07/2021 | Please select | |
| 77 | 19/EM/0357 | 270397 | A Phase 2, Double-Blind, Randomized, Parallel-Group Study Evaluating the Efficacy, Safety, and Tolerability of Obeticholic Acid, Administered Alone or in Combination with Bezafibrate, in Subjects with Primary Biliary Cholangitis who had an Inadequate Response or who were Unable to Tolerate Ursodeoxycholic Acid | 07/12/2020 | 07/12/2020 | 29/11/2019 | 18/12/2020 | 20/01/2021 | 12/05/2021 | | NHS Provider | Initial set up was suspended due to COVID-19. The study still hasn't been given the green light from NHS pharmacy because of a backlog with the amount of studies needing pharmacy input |
| 78 | 20/SC/0335 | 286668 | An open-label, randomized study to assess the relative bioavailability (BA) and bioequivalence (BE) of fixed-dose combination (FDC) formulations of niraparib plus abiraterone acetate (AA) compared to niraparib and AA co-administered as single agents in men with prostate cancer | 21/07/2020 | 01/03/2021 | 17/11/2020 | 21/05/2021 | 21/05/2021 | 24/05/2021 | 19/07/2021 | Sponsor | Delays were caused by contracting delays with sponsor. No patient was identified that meet the strict eligibility criteria until July 2021 |
| 79 | 20/NE/0283 | 286210 | An Open-Label, Randomized, Controlled, Phase 2 Study to Evaluate the Safety and Efficacy of Pegcetacoplan in the Treatment of Post Transplant Recurrence of C3G or IC-MPGN | 27/07/2020 | 26/04/2021 | 04/02/2021 | 13/05/2021 | 13/05/2021 | 14/05/2021 | | Neither | This study is looking into an ultra rare disease and for this reason, no patient has presented to the team who fits the eligibility criteria |
| 80 | 21/NE/0005 | 277964 | The effect of residual beta-cell function on the glucose-lowering potential of mealtime whey protein supplementation in people with diabetes. | 01/09/2020 | 04/05/2021 | 19/02/2021 | 19/05/2021 | 19/05/2021 | 19/05/2021 | | NHS Provider | Recruitment has been delayed due to staff illness |
| 81 | 20/NE/0270 | 286609 | Phase 1/2a Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination with Talazoparib in Advanced Solid Tumors with ATR inhibitor Sensitizing Mutations | 26/08/2020 | 09/04/2021 | 22/12/2020 | 07/05/2021 | 10/05/2021 | 10/05/2021 | 18/05/2021 | Please select | |

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| 82 | 20/LO/0963 | 281310 | Randomized, double-blind, phase 3 study of tucatinib or placebo in combination with ado-trastuzumab emtansine (T-DM1) for subjects with unresectable locally-advanced or metastatic HER2+ breast cancer (HER2CLIMB-02) | 07/09/2020 | 02/02/2021 | 23/10/2020 | 20/05/2021 | 21/05/2021 | 21/05/2021 | | Sponsor | Delays caused by contracting issues with sponsor - when study was submitted the sponsor was Seattle Genetics, company changed company name to SeaGen which required additional vendor assessments and finance reviews and assurances to be put into place, causing delays. Delays to recruitment have been caused by staffing within in the Cancer Team |
| 83 | 20/WM/0195 | 268363 | A multi-centre phase II trial of GvHD prophylaxis following unrelated donor stem cell transplantation comparing Thymoglobulin vs. Calcineurin inhibitor or Sirolimus-based post-transplant cyclophosphamide | 20/11/2020 | 29/04/2021 | 25/09/2020 | 21/05/2021 | 24/05/2021 | 24/05/2021 | | NHS Provider | Delays to recruitment have been caused by complications within set up from Pharmacy |
| 84 | 20/LO/1307 | 291610 | A multi-center, randomized, double-blind, placebo-controlled, parallel group, phase III study to evaluate the efficacy and safety of LNP023 in primary IgA nephropathy patients | 20/04/2021 | 20/04/2021 | 08/02/2021 | 27/05/2021 | 28/05/2021 | 28/05/2021 | | Neither | No patients have been identified who meet the eligibility criteria |
| 85 | 20/SC/0448 | 290709 | Community participants with COPD or bronchiectasis and at risk of Respiratory Viral Infections including SARS-CoV-2: An open-label, multicentre feasibility study of an inhaled nitric oxide generating solution (RESP301) | 14/04/2021 | 14/04/2021 | 18/12/2020 | 06/05/2021 | 07/05/2021 | 07/05/2021 | | Sponsor | This study is on hold pending a substantial protocol amendment and the Newcastle site does not yet have green light to proceed |
| 86 | 21/LO/0056 | 1003503 | Interventional, randomized, double-blind, parallel-group, placebo-controlled delayed-start study to evaluate the the efficacy and safety of eptinezumab in patients with episodic Cluster Headache (eCH). | 11/01/2021 | 06/05/2021 | 25/02/2021 | 24/05/2021 | 24/05/2021 | 24/05/2021 | 27/08/2021 | NHS Provider | Pharmacy green light was not given until the middle of August 2021 and the first patient was consented on 27th August 2021 |
| 87 | 21/WA/0008 | 283679 | A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, ACTIVE COMPARATORCONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FARICIMAB IN PATIENTS WITH MACULAR EDEMA SECONDARY TO CENTRAL RETINAL OR HEMIRETINAL VEIN OCCLUSION | 23/02/2021 | 20/04/2021 | 26/03/2021 | 21/05/2021 | 21/05/2021 | 21/05/2021 | 17/06/2021 | Please select | |
| 88 | 20/EM/0237 | 266746 | Acceptance and Commitment Therapy for Young Brain Tumour Survivors: An Acceptability and Feasibility Trial | 22/03/2021 | 29/04/2021 | 24/11/2020 | 14/05/2021 | 14/05/2021 | 14/05/2021 | | Neither | Delays to recruitment have been caused by COVID sickness within the research team |
| 89 | 21/YH/0071 | 295903 | Phase 2/3, Placebo-Controlled, Randomized, Observer-Blinded, Study to Evaluate to the Safety, Tolerability and Immunogenicity of SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) against COVID-19 IN Healthy Pregnant Women 18 years of Age and Older. | 24/03/2021 | 25/05/2021 | 21/04/2021 | 25/05/2021 | 25/05/2021 | 25/05/2021 | 24/06/2021 | Please select | |

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| 90 | 21/NW/0125 | 294164 | A RANDOMIZED, OBSERVER-BLIND, CONTROLLED, SUPERIORITY STUDY TO COMPARE THE IMMUNOGENICITY AGAINST COVID-19, OF VLA2001 VACCINE TO AZD1222 VACCINE, IN ADULTS | 03/03/2021 | 30/04/2021 | 20/04/2021 | 06/05/2021 | 07/05/2021 | 07/05/2021 | 10/05/2021 | Please select | |
| 91 | 21/WA/0066 | 253665 | A randomised crossover design study comparing the pharmacokinetics and pharmacodynamics of two single oral doses of aspirin (75 mg v150mg) in pregnant women at risk of pre-eclampsia. | 07/08/2018 | 23/06/2021 | 30/03/2021 | 23/06/2021 | 25/06/2021 | 25/06/2021 | 22/07/2021 | Please select | |
| 92 | 19/SC/0599 | 270649 | A Phase 1b Study of ASP1948, Targeting an Immune Modulatory Receptor, as a Single Agent and in Combination with Nivolumab in Subjects with Advanced Solid Tumours | 26/04/2021 | 26/04/2021 | 03/03/2020 | 09/06/2021 | 15/06/2021 | 15/06/2021 | 03/08/2021 | Sponsor | Set up was delayed as the contracting team had to wait for sponsor to sign. No patients were identified until August 2021 that met the eligibility criteria |
| 93 | 21/NE/0020 | 275595 | A pragmatic, multicentre, placebo-controlled, 3-arm, double-blinded, randomised controlled trial, incorporating an internal pilot, to determine the role of bronchodilators in preventing exacerbations of bronchiectasis | 11/11/2019 | 14/06/2021 | 10/03/2021 | 14/06/2021 | 14/06/2021 | 17/06/2021 | 22/09/2021 | Sponsor | Study was delayed recruiting their first patient due to confirmation from sponsor of study opening at site (Greenlight) |
| 94 | 19/LO/1690 | 240451 | Visualizing and Measuring Facial Expressions of Children with Cleft Lip using 3D Surface Data obtained from Depth Sensors | 23/03/2021 | 24/03/2021 | 14/11/2019 | 01/06/2021 | 09/06/2021 | 09/06/2021 | | Sponsor | Initial delays were caused by the sponsor querying items within the contract. No patient have been identified that meet the eligibility criteria |
| 95 | 19/LO/1585 | 263041 | Compression Hosiery to Avoid Post-Thrombotic Syndrome | 17/12/2019 | 03/06/2021 | 24/10/2019 | 24/05/2021 | 25/06/2021 | 29/06/2021 | | NHS Provider | Recruitment has been difficult due to staffing issues |
| 96 | 21/LO/0186 | 286735 | Effects of tele-rehabilitation multimodal lifestyle intervention on function capacity, cardiovascular health and quality of life inpatients with peripheral artery disease from low socioeconomic areas: a pilot randomized controlled trial Telehealth EXercise Training in peripheral arterial disease –The TEXT-PAD study | 01/07/2020 | 06/05/2021 | 22/04/2021 | 05/08/2020 | 11/06/2021 | 11/06/2021 | 15/09/2021 | NHS Provider | Recruitment was delayed due to staff issues due to COVID and long term sick |
| 97 | 20/NW/0260 | 1003209 | A Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study of AG-881 in Subjects With Residual or Recurrent Grade 2 Glioma With an IDH1 or IDH2 Mutation | 20/01/2021 | 20/01/2021 | 17/07/2020 | 15/06/2021 | 21/06/2021 | 21/06/2021 | 15/09/2021 | Sponsor | The sponsor changed halfway throught the contract which caused huge delays. The study was late receiving the Green Light which caused delays with recruitment |
| 98 | 20/NW/0340 | 1003335 | A PHASE IIIB MULTICENTER, RANDOMIZED, DOUBLE-BLIND, CONTROLLED STUDY TO EVALUATE THE EFFICACY, SAFETY AND PHARMACOKINETICS OF A HIGHER DOSE OF OCRELIZUMAB IN ADULTS WITH PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS | 22/09/2020 | 19/05/2021 | 18/09/2020 | 19/05/2021 | 20/05/2021 | 08/06/2021 | | Sponsor | The research team are currently awaiting Doctor training before they are able to gain green light from the sponsor |

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| 99 | 20/WS/0057 | 277361 | Erythropoietin and Darbepoetin in Neonatal Encephalopathy (EDEN) study | 20/10/2020 | 19/05/2021 | 27/05/2020 | 01/06/2021 | 02/06/2021 | 02/06/2021 | | NHS Provider | The research team have been unable to recruit to EDEN due to the pharmacy production team not being ready |
| 100 | 21/EM/0041 | 281071 | Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge: The Hummingbird Study | 13/11/2020 | 20/05/2021 | 06/04/2021 | 01/06/2021 | 01/06/2021 | 01/06/2021 | 08/06/2021 | Please select | |
| 101 | 20/YH/0300 | 287046 | A Prospective, Multi-Center Study of the Braive™ Growth Modulation System When Used in the Treatment of Pediatric Patients Diagnosed with Juvenile or Adolescent Idiopathic Scoliosis (BRAIVE IDE Study) | 26/04/2021 | 09/06/2021 | 04/01/2021 | 11/06/2021 | 11/06/2021 | 14/06/2021 | 12/08/2021 | Please select | |
| 102 | 21/WM/0013 | 283141 | Hysteroscopic Excision of Leiomyoma and Polyp in Infertility - two randomised controlled trials | 21/05/2021 | 07/06/2021 | 10/02/2021 | 09/06/2021 | 09/06/2021 | 17/06/2021 | | Neither | Low number of patients are presenting at the hospital who meet the strict eligibility criteria |
| 103 | 21/SC/0200 | 300677 | A Phase II/III Partially Double-Blinded, Randomised, Multinational, Active-Controlled Study in Both Previously Vaccinated and Unvaccinated Adults Ages 30 and Above to Determine the Safety and Immunogenicity of AZD2816, a Vaccine for the Prevention of COVID-19 Caused by Variant Strains of SARS-CoV-2 | 15/06/2021 | 29/06/2021 | 22/06/2021 | 29/06/2021 | 29/06/2021 | 29/06/2021 | 07/07/2021 | Please select | |
| 104 | 20/NE/0248 | 270777 | Obeticholic acid for the Amelioration of Cognitive Symptoms trial - 1 | 13/09/2019 | 08/03/2021 | 19/01/2021 | 31/03/2021 | 01/04/2021 | 01/04/2021 | 24/06/2021 | Neither | Delays to recruitment was caused because the patient needed an MRI scan as per protocol, and was booked into the first one that came available |
| 105 | 21/YH/0026 | 289207 | The HistoSonics System for treatment of primary and metastatic livertumors using histotripsy. | 16/09/2020 | 24/05/2021 | 16/04/2021 | 24/05/2021 | 25/05/2021 | 09/06/2021 | 08/07/2021 | Please select | |
| 106 | 20/LO/0821 | 281982 | AN OPEN-LABEL, MULTICENTER, ROLLOVER STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF LONG-TERM GANTENERUMAB ADMINISTRATION IN PARTICIPANTS WITH ALZHEIMER'S DISEASE | 18/08/2020 | 10/06/2021 | 23/07/2020 | 10/06/2021 | 18/06/2021 | 18/06/2021 | 30/06/2021 | Please select | |
| 107 | 19/SC/0112 | 259372 | Adalimumab in Juvenile Idiopathic Arthritis-associated Uveitis Stopping Trial (ADJUST) | 04/05/2021 | 02/06/2021 | 12/11/2019 | 10/06/2021 | 14/06/2021 | 16/07/2021 | | Sponsor | This study has not recruited a patient because the machine sent to ophthalmology as part of the study, does not work and this is also a problem at other sites. After many virtual meetings, it has been decided with sponsor to now use a paper alternative. The team are hopeful to recruit soon |
| 108 | 20/EM/0159 | 278357 | Robotic Arthroplasty: a Clinical and cost Effectiveness Randomised controlled trial (RACER) | 16/10/2020 | 01/07/2021 | 29/07/2020 | 01/07/2021 | 09/07/2021 | 09/07/2021 | | Neither | No patient has been identified due to the way the study logistics work the team will only approach patients who are attending a pre-op clinic – We have 242 patients on the waiting list who we are in the process of screening and checking when pre-op appointments - this is quite time consuming and has been made more difficult due to reduced staffing |

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| 109 | 20/SC/0299 | 283235 | A Phase 1b/2, Open-Label Trial to Assess the Safety and Preliminary Efficacy of Epcoritamab (GEN3013; DuoBody® CD3xCD20) in Combination with Other Agents in Subjects with B-cell Non-Hodgkin Lymphoma | 09/12/2020 | 16/06/2021 | 01/10/2020 | 15/07/2021 | 19/07/2021 | 19/07/2021 | | NHS Provider | The research team are yet to recruit to this study due to a significant nursing capacity issue within the team, which is related to maternity leave and long term sickness of our chemotherapy trained nursing staff |
| 110 | 21/FT/0003 | 291436 | Randomised, double-blind, placebo-controlled, parallel group Phase 3 study to evaluate the efficacy, safety, and tolerability of SAR440340/REGN3500/itepekimab (anti-IL-33 mAb) in patients with moderate-to-severe chronic obstructive pulmonary disease (COPD) | 25/01/2021 | 28/06/2021 | 15/03/2021 | 05/07/2021 | 06/07/2021 | 06/07/2021 | 30/09/2021 | Both | Delays were caused in receiving sponsor green light, due to a difficulties in arranging a mutual agreeable SIV date. The team were also waiting for the PI and Sub-PI to complete training on third party vendors before sponsor would sign off the site as active |
| 111 | 21/ES/0041 | 1003675 | A Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Ravulizumab in Adult Participants Who Have Thrombotic Microangiopathy Associated With a Trigger | 24/02/2021 | 01/07/2021 | 12/05/2021 | 04/07/2021 | 05/07/2021 | 06/07/2021 | | Neither | This study deals with a rare life threatening disease. No eligible patients have been identified |
| 112 | 21/NW/0017 | 291746 | BabyBreathe Trial: A randomised controlled trial of a complex intervention to prevent return to smoking postpartum | 31/03/2021 | 05/07/2021 | 16/03/2021 | 06/07/2021 | 06/07/2021 | 06/07/2021 | | Both | After C&C was issued the SIV took far longer than expected to schedule due to AL/Staff availability. As the study relies on the health visitor team to support the trial they needed to be appropriately trained before sponsor would open Newcastle as a site. |
| 113 | 20/SC/0018 | 258872 | A randomised controlled trial assessing if microsurgical nerve repair offers clinical benefit and cost effectiveness (in terms of patient–reported hand function, sensory recovery and adverse events) over exploration and washout without microsurgical nerve repair in adult patients with recent traumatic digital nerve injury. | 14/04/2021 | 17/06/2021 | 13/02/2020 | 01/07/2021 | 06/07/2021 | 06/07/2021 | | Neither | The team have seen only one appropriate patient since opening the study and they declined to take part. The team have noted that over the last 2 months, they have not seen the normal number of patients with digital nerve injuries. |
| 114 | 21/HRA/0489 | 294480 | OCTAVE: Observational Cohorts Trial - T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2 | 24/05/2021 | 23/06/2021 | 12/02/2021 | 05/07/2021 | 06/07/2021 | 06/07/2021 | 16/08/2021 | Please select | |
| 115 | 20/EE/0077 | 278155 | A phase 3 multicentre, double-blind, randomised, placebo-controlled study to evaluate the efficacy, safety, and tolerability of Rozanolixizumab in adult study participants with persistent or chronic primary immune thrombocytopenia (ITP) | 05/05/2020 | 08/06/2021 | 20/04/2020 | 11/08/2021 | 24/08/2021 | 24/08/2021 | | NHS Provider | Delays in set up and recruitment have been caused by Pharmacy production being unable to support the study. The team have had to find an alternative drug prep team |
| 116 | 20/NW/0470 | 275219 | Metformin to prevent progression of sarcopenia and frailty in older people – a randomised controlled proof of concept trial | 10/08/2020 | 27/07/2021 | 07/01/2021 | 11/08/2021 | 19/08/2021 | 19/08/2021 | 16/09/2021 | Please select | |

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| 117 | 19/EE/0377 | 266504 | Trial of Ondansetron as a Parkinson's HAllucinations Treatment | 26/08/2020 | 12/07/2021 | 17/06/2020 | 19/08/2021 | 19/08/2021 | 19/08/2021 | | NHS Provider | SIV was initially planned for Early September but due to clinical requirements of the PI and Sub-I the SIV was pushed back to October, the study team are actively searching for recruits |
| 118 | 20/NE/0097 | 265147 | A Randomised Feasibility n-of-1 Trial of Weekly-Interval Red Cell Transfusion in myelodysplastic syndromes | 01/07/2019 | 06/08/2021 | 18/08/2020 | 06/08/2021 | 20/08/2021 | 20/08/2021 | | Please select | |
| 119 | 20/YH/0232 | 280105 | ATNEC - Axillary management in T1-3N1M0 breast cancer patients with needle biopsy proven nodal metastases at presentation after neoadjuvant chemotherapy | 16/11/2020 | 15/07/2021 | 22/10/2020 | 29/07/2021 | 03/08/2021 | 03/08/2021 | 23/09/2021 | Please select | |
| 120 | 21/WM/0017 | 287442 | A Phase 2a/2b Randomized Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Volixibat in Adult Women with Intrahepatic Cholestasis of Pregnancy and Elevated Serum Bile Acid Concentrations (OHANA) | 25/03/2021 | 27/08/2021 | 08/03/2021 | 30/08/2021 | 31/08/2021 | 31/08/2021 | | Please select | |
| 121 | 20/EE/0252 | 276415 | Pharmacological management of seizures post traumatic brain injury (MAST) | 31/03/2021 | 02/06/2021 | 20/01/2021 | 20/07/2021 | 09/08/2021 | 09/08/2021 | 20/08/2021 | NHS Provider | Delays to confirmation and capacity were caused by staff annual leave after contract was signed and PI wanting to see the first participant on their return from leave |
| 122 | 21/FT/0058 | 293068 | A Phase 1 Study Exploring the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of INCB099318 in Participants With Select Advanced Solid Tumors | 22/04/2021 | 11/08/2021 | 17/05/2021 | 19/08/2021 | 19/08/2021 | 19/08/2021 | | Please select | |
| 123 | 21/FT/0069 | 290279 | A multicenter, randomized, double-blind, parallel group, placebo-controlled study to evaluate the efficacy and safety of iptacopan (LNP023) in complement 3 glomerulopathy | 06/05/2021 | 29/07/2021 | 07/07/2021 | 12/08/2021 | 16/08/2021 | 16/08/2021 | 07/09/2021 | Please select | |
| 124 | 21/WS/0003 | 286426 | COLO-DETECT: A Randomised Controlled Trial of Lesion Detection at Colonoscopy Using the GI Genius™ Artificial Intelligence Platform | 18/05/2021 | 13/08/2021 | 25/01/2021 | 16/08/2021 | 16/08/2021 | 16/08/2021 | | Please select | |
| 125 | 21/NW/0109 | 1003688 | A MULTICENTER, OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AVONELLE-X) | 15/06/2021 | 30/07/2021 | 18/06/2021 | 03/08/2021 | 04/08/2021 | 04/08/2021 | 05/08/2021 | Please select | |
| 126 | 18/EM/0190 | 243165 | A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome | 08/10/2018 | 24/08/2021 | 14/09/2018 | 08/09/2021 | 09/09/2021 | 09/09/2021 | | Please select | |

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| 127 | 18/WM/0227 | 235254 | The Carboprost or Oxytocin Postpartum haemorrhage Effectiveness Study. Carboprost vs Oxytocin as the First Line Treatment of Primary Postpartum Haemorrhage; A phase IV, double-blind, double-dummy, randomised controlled trial. | 16/08/2019 | 28/05/2021 | 28/11/2018 | 07/09/2021 | 08/09/2021 | 08/09/2021 | | Sponsor | Delays were caused by the sponsor not providing signatures after being chased by goverance team over a period of many weeks |
| 128 | 19/SC/0456 | 266074 | A Phase 1b/2 Randomised, Placebo-controlled, Dose-ranging Study to Evaluate Safety, Tolerability and Immunogenicity of a Chimpanzee Adenovirus (ChAdOx1)-vectored Multigenotype High Risk Human Papillomavirus (hrHPV) Vaccine and Modified Vaccinia Ankara (MVA)-vectored Multigenotype hrHPV Vaccine in Women with Low-grade HPV-related Cervical Lesions | 23/10/2019 | 18/08/2021 | 13/08/2020 | 13/09/2021 | 15/09/2021 | 15/09/2021 | | Please select | |
| 129 | 19/WS/0123 | 227793 | Motor Neurone Disease Systematic Multi-arm Adaptive Randomised Trial (MND-SMART) | 10/02/2020 | 22/02/2021 | 14/10/2019 | 07/07/2021 | 20/09/2021 | 20/09/2021 | | Both | This study was submitted to R&D in February 2021, shortly after an amendment was submitted that required an additional finance review, the contract was at signature stage when the Newcastle pharmacy team expressed capacity concerns and said they were unable to support the study at the time. Pharmacy reconfirmed capacity to support the study on Friday 17th September 2021 by email |
| 130 | 20/SC/0041 | 275334 | Study title: OPtimizaTIon of Left MAin PCI with IntravascuLar Ultrasound. The OPTIMAL Randomized Controlled Trial | 27/02/2020 | 06/08/2021 | 15/06/2020 | 02/09/2021 | 02/09/2021 | 02/09/2021 | | Please select | |
| 131 | 18/SC/0028 | 235714 | A Phase 1 Multicenter, Open-Label Study to Assess The Safety, Pharmacokinetics And Preliminary Efficacy of CC-92480 in Combination With Dexamethasone in Subjects With Relapsed And Refractory Multiple Myeloma | 30/09/2020 | 02/08/2021 | 08/03/2018 | 28/09/2021 | 28/09/2021 | 28/09/2021 | | Both | Initial finance issues sent to sponsor on 16th August with the contract going back and forth between sponsor and Trust until agreement on 16th September, when final contract was sent to sponsor for signature. Sponsor signed contract on 28th September (contract sent for Trust signature same day) |
| 132 | 19/EE/0228 | 260350 | Sugar or Salt (SOS) trial: Hyperosmolar therapy in traumatic brain injury | 16/10/2020 | 02/08/2021 | 18/12/2019 | 15/09/2021 | 15/09/2021 | 15/09/2021 | | Sponsor | Sponsor delays to contract signing |
| 133 | 21/LO/0449 | 1003652 | Randomised controlled trial of plasma cell depletion for severe Graves' disease | 29/10/2020 | 25/08/2021 | 08/07/2021 | 08/09/2021 | 15/09/2021 | 15/09/2021 | | Please select | |
| 134 | 20/LO/1207 | 282292 | A Double-blind Randomized, Placebo-Controlled Study and Open-label Long Term Extension to Evaluate the Efficacy and Safety of Elafibranor 80 mg in Patients with Primary Biliary Cholangitis with Inadequate Response or Intolerance to Ursodeoxycholic Acid | 30/12/2020 | 24/08/2021 | 17/02/2021 | 02/09/2021 | 03/09/2021 | 03/09/2021 | | Please select | |
| 135 | 20/EE/0294 | 288140 | A Phase 3, Randomized, Double-blind, Multicenter, Placebo-Controlled Study of Inebilizumab Efficacy and Safety in IgG4 Related Disease | 11/01/2021 | 30/04/2021 | 04/02/2021 | 20/09/2021 | 21/09/2021 | 21/09/2021 | | Sponsor | Sponsor delays with contracting queries |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 136 | 21/PR/0752 | 280032 | Methodological validation of an intermittent shuttle walking protocol in the context of pulmonary rehabilitation in patients with Chronic Obstructive Pulmonary Disease | 20/01/2021 | 10/09/2021 | 23/07/2021 | 13/09/2021 | 13/09/2021 | 13/09/2021 | | Please select | |
| 137 | 21/NS/0007 | 291857 | Multi-centre prospective observational cohort study: To assess the performance of single use duodenoscope | 19/04/2021 | 27/07/2021 | 11/02/2021 | 01/09/2021 | 01/09/2021 | 01/09/2021 | | Please select | |
| 138 | 21/NE/0077 | 286650 | A double-blind, placebo-controlled, study to evaluate the efficacy and safety of 24 weeks treatment with REN001 in patients with Primary Mitochondrial Myopathy (PMM) | 21/04/2021 | 16/08/2021 | 12/05/2021 | 16/09/2021 | 16/09/2021 | 16/09/2021 | | Please select | |
| 139 | 19/WA/0019 | 247285 | ROSSINI 2: A Phase III, multi-arm, multi-stage (MAMS) pragmatic, blinded (patient and outcome assessor) multicentre, randomised controlled trial (RCT) with an internal pilot, to evaluate the use of three in-theatre interventions, alone or in combination, to reduce SSI rates in patients undergoing abdominal surgery. | 18/06/2021 | 11/08/2021 | 01/02/2019 | 07/09/2021 | 08/09/2021 | 08/09/2021 | 09/09/2021 | Please select | |
| 140 | 21/YH/0033 | 290847 | Breathing Retraining for Asthma Trial of Home Exercises for Teenagers; repurposing, refining and feasibility – Stage 3 | 01/07/2021 | 28/07/2021 | 16/04/2021 | 03/09/2021 | 03/09/2021 | 03/09/2021 | | Please select | |
| 141 | 21/SC/0261 | 300456 | Post-approval follow-up for the COV001 and 002 trials, to determine the long-term safety and character of immunological response to the ChAdOx1 nCoV-19 coronavirus vaccine | 10/08/2021 | 13/09/2021 | 20/08/2021 | 14/09/2021 | 15/09/2021 | 16/09/2021 | 23/09/2021 | Please select | |
| 142 | 20/LO/1289 | 1003429 | Efficacy and Safety Study of Vatiquinone for the Treatment of Refractory Epilepsy in Subjects with Mitochondrial Disease | 16/12/2020 | 29/06/2021 | 20/01/2021 | 21/07/2021 | 22/07/2021 | 22/07/2021 | 28/09/2021 | Both | Delays to recruitment were caused by sponsor sorting out logins for study staff and site files delays. The PI also caused delays as he preferred the study to go active after his annual leave as the cohort of children are hard to recruit over the summer school holidays |
| 143 | 18/NW/0699 | 241427 | TACE-3: A two-arm multi-stage (TAMS) seamless phase II/III randomised trial of nivolumab in combination with TACE/TAE for patients with intermediate stage HCC | 24/09/2019 | 29/10/2020 | 21/03/2019 | 02/07/2021 | 15/07/2021 | 15/07/2021 | | Both | Study suffered a number of set backs when submitted to R&D, including a delay in finance queries being responded to by CTC and contracting delays with sponsor. Delays to recruitment have been caused by sickness within the research team |
| 144 | 19/LO/0043 | 255663 | A long-term extension trial of the Phase III lipid-lowering trials to assess the effect of long-term dosing of inclisiran given as subcutaneous injections in subjects with high cardiovascular risk and elevated LDL-C | 16/03/2021 | 09/07/2021 | 01/03/2019 | 09/07/2021 | 12/07/2021 | 12/07/2021 | 13/08/2021 | Please select | |