# PERFORMANCE IN INITIATING CLINICAL RESEARCH (Q3, 2015/16)

| Research Ethics Committee Reference Number | Name of Trial | Date of Receipt of Valid Research Application | Date of First Patient Recruited | Benchmark Met? | Reason for not meeting benchmark |
|---|---|---|---|---|---|
| 13/WS/0056 | Cancer and Venous Access (CAVA) A randomised controlled trial with associated qualitative research of venous access devices for the delivery of long-term chemotherapy | 03/02/2015 | 24/03/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1833 | Pilot study to evaluate diffusion weighted MRI (DWMRI) Whole Body MRI in relapsed Multiple Myeloma at 3T: test re test, early response assessment and exploratory imaging of renal function | 16/02/2015 | 01/04/2015 | Yes | Study met 70-day benchmark |
| 14/SC/1206 | The Efficacy and Cost effectiveness of Real Time Ultrasound Elastography in The Investigation Of Thyroid Nodules and the diagnosis of thyroid cancer. | 09/03/2015 | 21/04/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1060 | Assessment of digestion and metabolism following altered macronutrient intake | 29/07/2015 | 17/08/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0780 | GLP-1 Receptor Agonist interVeniton for poor responders after barIAtric Surgery: The GRAVITAS trial. | 10/12/2015 | | n/a | 70-day benchmark not yet expired |
| 15/LO/0813 | Are gut hormone changes why the long-limb gastric bypass is more effective than the standard-limb gastric bypass in improving type 2 diabetes mellitus? The LONG LIMB trial | 28/07/2015 | 31/07/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1295 | One Stop Vein Clinic - Evaluating the Feasibility and Acceptance of a One Stop Vein Clinic | 26/05/2015 | 29/09/2015 | No | Several patients were identified but were screening failures. |
| 14/EE/0192 | Neuromuscular Electrical Stimulation (NMES) in patients with critical limb ischaemia | 16/06/2015 | 12/10/2015 | No | Study team identified 3 suitable patients but declined to participate. Critical limb ischaemia (CLI) is a relatively rare presentation. |
| 14/SC/0032 | PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS | 30/07/2015 | 08/10/2015 | Yes | Study met 70-day benchmark |
| 14/SC/0033 | PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS | 30/07/2015 | 07/10/2015 | Yes | Study met 70-day benchmark |
| 14/EM/1302 | Neuromuscular Electrical Stimulation for the treatment of Diabetic Peripheral Neuropathy. | 13/02/2015 | 10/04/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0620 | Dosing of Electrical Stimulation in Venous Insufficiency (DESiVI) | 10/09/2015 | 29/10/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0140 | CLEANER Assessment of efficacy and safety for a new wound dressing URGO 310 3166 in the local treatment of venous or mixed leg ulcers: a European, randomised clinical trial. | 04/06/2015 | 23/07/2015 | Yes | Study met 70-day benchmark |
| 15/EM/0021 | A randomised, double blind, placebo controlled multicenter trial, examining the effect of Natrox? on the rates of healing for chronic diabetic foot ulcers | 23/07/2015 | 08/09/2015 | Yes | Study met 70-day benchmark |
| 12/YH/0504 | Assessment of the efficacy and safety of a new wound dressing in the local treatment of diabetic foot ulcers: A Prospective, randomised, controlled, doubleblind, European multicentre clinical trial. | 12/02/2015 | 31/03/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1185 | Using Step Count to Enhance Daily Physical Activity in Pulmonary Hypertension | 16/10/2015 | 23/11/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2044 | The role of intrinsic cardiac autonomic nervous system in human arrhythmogensis | 16/03/2015 | 21/04/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2143 | Measurement of low-energy stimulation in patients with atrial fibrillation | 15/05/2015 | 11/06/2015 | Yes | Study met 70-day benchmark |
| 14/LO/0117 | Ablation versus anti-arrhythmic therapy for reducing all hospital episodes from recurrent atrial fibrillation. | 27/03/2015 | 22/04/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1351 | The prognostic value of global longitudinal strain of the left ventricle in the risk assessment of patients with non-ST elevation myocardial infarction | 23/10/2015 | 13/11/2015 | Yes | Study met 70-day benchmark |
| 14/NE/1109 | Cardiac Resynchronization Therapy Efficacy Enhancements (CRTee) | 30/10/2015 | 19/11/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0181 | A multicentre randomised controlled trial of compression therapy following endovenous thermal ablation of varicose veins | 30/04/2015 | 18/05/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2060 | A PROSPECTIVE MULTICENTRE STUDY OF EFFECTIVENESS OF RIPPLE MAPPING FOR ATRIAL TACHYCARDIA ABLATION | 15/01/2015 | 02/02/2015 | Yes | Study met 70-day benchmark |
| 15/YH0333 | Preoperative Pocket Echocardiography Trial | 16/07/2015 | 31/07/2015 | Yes | Study met 70-day benchmark |

| | | | | | |
|---|---|---|---|---|---|
| 14/LO1370 | Macitentan in thE tReatment of Inoperable chronic Thromboembolic pulmonary hypertension (Open-Label) | 12/11/2015 | 24/11/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1779 | Incentive in Diabetic Eye Assessment by Screening (IDEAS) Trial | 12/03/2015 | 19/03/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0769 | Left Atrial Appendage Occlusion Study III | 09/09/2015 | 10/09/2015 | Yes | Study met 70-day benchmark |
| 13/NI/0160 | Management of myocardial injury After NoncArdiac surgGEry (MANAGE) | 25/03/2015 | | No | Study team have screened numeorus patients, but they did not meet the inclusion criteria and therefore were not suitable to be recruited to the study. |
| 15/NE/0314 | RCT of compression therapy following foam sclerotherapy | 16/12/2015 | | n/a | 70-day benchmark not yet expired |
| 15/WS/0147 | A Multicenter, Open Label, Prospective, Post Approval Study of the INCRAFT® AAA Stent Graft System in Subjects with Abdominal Aortic Aneurysms | 15/12/2015 | | n/a | 70-day benchmark not yet expired |
| 14/LO/1800 | The Efficacy and Mechanism Evaluation of Treating Idiopathic Pulmonary fibrosis with the Addition of Co-trimoxazole (EME-TIPAC) | 27/10/2015 | 12/11/2015 | Yes | Study met 70-day benchmark |
| 13/EE/0038 | HALT-IT - Tranexamic acid for the treatment of gastrointestinal bleeding: an international randomised, double blind placebo controlled trial | 09/08/2015 | 03/10/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0460 | SSAT058: A phase IV, openlabel, multi centre pilot study to assess changes in cerebral function parameters in patients without perceived Central Nervous System (CNS) symptoms when switched from tenofovir/emtricitabine/efavirenz (Atripla®) to a fixed dose combination of tenofovir/emtricitabine/rilpivirine (Eviplera®). | 20/10/2015 | 15/12/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1493 | A phase IV open-label, multi-centre, randomised, dual-arm, pilot study to assess the feasibility of switching individuals receiving Efavirenz with continuing Central Nervous System (CNS) toxicity, to Dolutegravir | 22/01/2015 | 12/03/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2078 | A Phase 1, first in man, study to assess the safety, pharmacokinetic profile and antiretroviral efficacy of C34-PEG4-Chol, a novel peptide fusion inhibitor for the treatment of HIV-infection | 26/02/2015 | 14/04/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1864 | The CNS Integrase Inhibitor Study | 12/06/2015 | 14/07/2015 | Yes | Study met 70-day benchmark |
| 14/NE/1246 | CUT*HIVTHER 001 - A randomized phase I/II study to assess the safety and immunogenicity of the DNAGTU vaccine administered by two novel routes compared to placebo in HIV-infected patients on antiretroviral therapy | 14/04/2015 | 15/05/2015 | Yes | Study met 70-day benchmark |
| 14/SC/1372 | Research In Viral Eradication of HIV Reservoirs A two-arm (proof of concept) randomised phase II trial | 24/11/2015 | 07/12/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0423 | An open label study to investigate the safety and efficacy of abacavir/lamivudine/dolutegravir and the pharmacokinetic profile of dolutegravir in HIV-infected patients of 60 years of age and older | 10/11/2015 | | n/a | 70-day benchmark not yet expired |
| 15/LO/0652 | A Phase 2b Randomized, Active-Controlled, Double-Blind Trial to Investigate Safety, Efficacy and Dose-response of BMS-955176, Given on a Backbone of Tenofovir/Emtricitabine, in Treatment-Naive HIV-1 Infected Adults | 14/08/2015 | | No | Sponsor closed recruitment 2 weeks after site got R&D Approval. Recruitment was competitive and study reached full recruitment. |
| 15/LO/0881 | A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects | 27/11/2015 | | n/a | 70-day benchmark not yet expired |
| 15/LO/1163 | A Phase 3b, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV-1 Infected Subjects who are Virologically Suppressed on Regimens containing ABC/3TC | 30/10/2015 | | n/a | 70-day benchmark not yet expired |
| 15/SC/0108 | A Phase Ia clinical trial to assess the safety and immunogenicity of MVA-EBO Z alone and a heterologous prime-boost immunisation with ChAd3-EBO Z and MVA-EBO Z in healthy UK volunteers | 21/05/2015 | 15/06/2015 | Yes | Study met 70-day benchmark |
| 15/SC/0386 | Safety and immunogenicity of a protein particle malaria vaccine candidate, R21, administered with and without Matrix-M1 in healthy UK volunteers | 29/10/2015 | 19/11/2015 | Yes | Study met 70-day benchmark |
| 15/SC/0267 | A Phase I, safety and immunogenicity trial of the heterologous prime-boost regimen combining the monovalent Zaire Ebola viral vector candidates ChAd3-EBO-Z and Ad26.ZEBOV in healthy UK adults | 30/08/2015 | 09/09/2015 | Yes | Study met 70-day benchmark |
| 14/SC/1056 | A multicentre randomised controlled trial to compare the efficacy of ex-vivo oxygenated hypothermic machine perfusion with non-oxygenated hypothermic machine perfusion of kidneys older than 50 years of age and donated after circulatory death | 04/03/2015 | 15/11/2015 | No | Site has no control over national scheme for allocation of deceased organs and there is no way to predict if and when we will be allocated organs for the study. |
| 12/EE/0230 | RITAZAREM: Rituximab vasculitis maintenance study - An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCAassociated vasculitis | 14/04/2015 | 02/07/2015 | No | Not possible to pre-screen these patients as study requires that they relapse, which can only be determined once they return later to clinic. Vasculitis is a rare condition. According to the Vasculitis UK, only 10-15 new cases per year (per million population) are being diagnosed with ANCA-associated vasculitis. |

| | | | | | |
|---|---|---|---|---|---|
| 15/LO/1011 | A Feasibility randomised controlled trial: Effects of oral sodium bicarbonate supplementation in patients on haemodialysis | 11/09/2015 | 19/11/2015 | Yes | Study met 70-day benchmark |
| 14/LO/0805 | Predictors of response to treatment with iron and erythropoietin in dialysis anaemia | 14/05/2015 | 07/07/2015 | Yes | Study met 70-day benchmark |
| 13/YH/0394 | Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease | 30/04/2015 | 11/06/2015 | Yes | Study met 70-day benchmark |
| 14/EM/0121 | An open label randomised multicentre controlled trial of RITUXImab and mycophenolate mofetil (MMF) without oral steroids for the treatment of LUPus nephritis | 08/04/2015 | 15/05/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1679 | Impact on Hypoglycaemia Awareness of Real Time CGM and Intermittent Continuous Glucose Data | 24/11/2015 | | n/a | 70-day benchmark not yet expired |
| 15/LO/1228 | An Open-Label Study to Evaluate the Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir with or without Dasabuvir in Adults with Genotype 1a or Genotype 4 Chronic Hepatitis C Virus (HCV) Infection, with Severe Renal Impairment (?) (RUBY-II) | 23/09/2015 | 14/12/2015 | No | The first two patients consented within the 70-day benchmark. Unfortunately both were screening failures due to genotyping issues which made them ineligible. |
| 15/LO/0743 | A phase I, randomised, double-blind, placebo-controlled, multicentre, ascending-dose trial to evaluate safety, tolerability and immunogenicity of Vaccine FP-02.2 in HBeAg-negative hepatitis B patients as an add-on treatment to entecavir or tenofovir | 25/08/2015 | 06/10/2015 | Yes | Study met 70-day benchmark |
| 14/WM/1262 | An Open Label Study of Sofosbuvir/GS5816 FixedDose Combination in Subjects with Chronic HCV Infection | 23/03/2015 | 27/04/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0153 | NACAH - The Mechanism of Action of N-AcetylCysteine for Reducingthe Risk of Infection in Alcoholic Hepatitis | 18/09/2015 | 14/10/2015 | Yes | Study met 70-day benchmark |
| 15/NW/0700 | M13-583 A Single-Arm, Open-Label Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 4, 5, or 6 Infection (ENDURANCE-4) | 23/11/2015 | 15/12/2015 | Yes | Study met 70-day benchmark |
| 15/NW/0871 | A Single-Arm, Open-Label, Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Renally-Impaired Adults with Chronic Hepatitis C Virus Genotype 1 – 6 Infection (EXPEDITION-4) | 10/12/2015 | | n/a | 70-day benchmark not yet expired |
| 10/H0302/51 | Improving the management and control of tuberculosis among hard to reach groups | 09/02/2015 | 21/04/2015 | No | First suitable patient identified 22 days after valid submission of study but eventually declined. Study team approached funder to discuss difficulties with screening. A patient was successfully recruited only 1 day after the benchmark of 70 days. |
| 13/WM/0364 | Targeted retreatment of incompletely recovered COPD exacerbations with ciprofloxacin: a double-blind, randomised, placebo-controlled, multicentre Phase III trial - WP4 | 23/10/2015 | | n/a | 70-day benchmark not yet expired |
| 14/NE/1072 | A PHASE II RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED BRONCHOSCOPY STUDY TO EVALUATE THE EFFECTS OF LEBRIKIZUMAB ON AIRWAY EOSINOPHILIC INFLAMMATION IN PATIENTS WITH UNCONTROLLED ASTHMA ON INHALED CORTICOSTEROIDS AND A SECOND CONTROLLER MEDICATION | 16/01/2015 | | No | Sponsor delay in activating site. Delays in Sponsor sending equipment needed for the study. First volunteer identified within 8 days of receiving final PIS. Dozens of volunteers approached since but were either inegible or declined. |
| 15/LO/0292 | PILOT STUDY OF HOME ACTIGRAPHY MONITORING IN MS | 01/04/2015 | 01/09/2015 | No | Specialist supplier did not deliver essential equipment to site in time. Sponsor has now ordered alternative equipment. |
| 14/NW/1076 | Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma (RESCUE-ASDH) Study Short Title RESCUE-ASDH trial. Version 1.0 | 18/03/2015 | 16/07/2015 | No | Sponsor recognised the difficulty in recruiting patients and new protocol has now been approved by REC. |
| 14/LO/0612 | Care of Late Stage Parkinsonism | 12/08/2015 | 08/12/2015 | No | Additional Information Governance requirement. |
| 14/NW/1427 | A Phase 3, Randomized Study Investigating the Safety of CVT-301 (Levodopa Inhalation Powder) in Parkinsons Disease Patients With Motor Response Fluctuations (OFF Phenomena) Compared to an Observational Cohort Control | 29/04/2015 | 12/07/2015 | No | Additional Information Governance requirement. |
| 13/LO/1224 | Assessing sensitivity to and tolerability of intravenous psilocybin in patients with treatment-resistant depression: A Pilot Study | 12/03/2015 | 21/04/2015 | Yes | Study met 70-day benchmark |
| 14/EM/1309 | The role of buspirone in LIDs in patients with Parkinson??s disease | 01/10/2015 | 26/10/2015 | Yes | Study met 70-day benchmark |
| 15/SC/0165 | A Single-Blinded, Randomized, Controlled Study to Evaluate the Safety and Effectiveness of EVICEL? Fibrin Sealant (Human) Compared to a Hydrogel Sealant as an Adjunct to Sutured Dural Repair | 24/09/2015 | 09/10/2015 | Yes | Study met 70-day benchmark |

| | | | | | |
|---|---|---|---|---|---|
| 14/LO/1994 | The AMARANTH study - A 24-month, Multicenter, Randomized, Double-blind, Placebo-controlled,Parallel-group, Efficacy, Safety, Tolerability, Biomarker, and Pharmacokinetic Study of AZD3293 in Early Alzheimer?s Disease | 18/06/2015 | | No | Sponsor took 36 days from R&D approval to issue greenlight. Site started to recruit immediately but had difficulties in finding potential patients meeting all the criteria. First patient consented and screened on 14/9. |
| 14/WS/1105 | REVEAL 101MS408 Multicenter study of Natalizumab v Fingolimod in MS | 26/03/2015 | | No | Sponsor delays in negotiating service support from MRI unit caused site recruitment to be suspended. Site confirmed they are ready to start recruitment once equipment is in place. |
| 13/NW/0714 | ECASS-4: ExTEND - European Cooperative Acute Stroke Study-4<br>Extending the time for Thrombolysis in Emergency Neurological Deficits | 03/02/2015 | 07/09/2015 | No | Sponsor delays in sending drug shipment. Once site had drugs, they immediately started screening but were unable to recruit prior to the 70 day benchmark. No eligible patients have been identified yet. |
| 14/WS/1146 | Multicenter, randomized, double-blind, double-dummy, active-comparator, event-driven, superiority phase III study of secondary prevention of stroke and prevention of systemic embolism (...) (ESUS) aspirin 100 mg - NAVIGATE ESUS | 30/07/2015 | 28/08/2015 | Yes | Study met 70-day benchmark |
| 14/WM/1055 | A prospective, multicenter, randomized, double blind, placebocontrolled, 2parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with FOLFIRI to placebo in combination with FOLFIRI | 09/03/2015 | 11/05/2015 | Yes | Study met 70-day benchmark |
| 13/LO/0326 | A RANDOMIZED, PHASE 3 STUDY OF GANETESPIB IN COMBINATION WITH DOCETAXEL VERSUS DOCETAXEL ALONE IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG ADENOCARCINOMA | 09/01/2015 | 10/03/2015 | Yes | Study met 70-day benchmark |
| 14/NE/1062 | PHOTOdynamic versus white light-guided treatment of non-muscle invasive bladder cancer: randomised trial of clinical and cost-effectiveness | 18/03/2015 | 14/05/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1291 | A phase II randomised study evaluating the biological and clinical effects of the combination of palbocicilib with Letrozole as neoadjuvant therapy in post-menopausal women with ER+ primary brest cancer | 18/09/2015 | 10/11/2015 | Yes | Study met 70-day benchmark |
| 13/EM/0349 | A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer. | 04/09/2015 | 23/10/2015 | Yes | Study met 70-day benchmark |
| 14/EM/1286 | A Randomized, Double-Blind Study of Ruxolitinib or Placebo in Combination With Regorafenib in Subjects With Relapsed or Refractory Metastatic Colorectal Cancer | 13/08/2015 | 30/09/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1728 | A Phase Ib Open Label Study of the Safety and Tolerability of ME-344 Given in Combination with Topotecan (Hycamtin?) in Patients with Solid Tumors | 03/03/2015 | 17/04/2015 | Yes | Study met 70-day benchmark |
| 14/NW/1027 | Evaluation of Sorafenib in combination with local microtherapy guided by GdEOBDTPA enhanced MRI in patients with inoperable hepatocellular carcinoma | 16/02/2015 | 01/04/2015 | Yes | Study met 70-day benchmark |
| 14/EM/1314 | Randomized, Blinded, Multicenter, Phase 2 Study Comparing Veliparib Plus FOLFIRI ? Bevacizumab Versus Placebo Plus FOLFIRI ? Bevacizumab in Previously Untreated Metastatic Colorectal Cancer | 17/07/2015 | 28/08/2015 | Yes | Study met 70-day benchmark |
| 13/LO/1618 | A Multicenter, Long-term Extension Study to Further Evaluate the Safety and Tolerability of Telotristat Etiprate (LX1606) | 04/08/2015 | 10/09/2015 | Yes | Study met 70-day benchmark |
| 14/NE/1214 | A Randomized, Open-Label, Multicenter, Phase 2 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy (?) or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (...) | 13/08/2015 | 18/09/2015 | Yes | Study met 70-day benchmark |
| 15/SC/0359 | M13-694: A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade (?) | 02/10/2015 | 03/11/2015 | Yes | Study met 70-day benchmark |
| 11/NW/0246 | A Randomised Multi-Stage Phase II/III Trial of Standard first-line therapy (sunitinib or pazopanib) Comparing Temporary Cessation with Allowing Continuation, in the treatment of locally advanced and/or metastatic Renal Cancer | 01/04/2015 | 20/04/2015 | Yes | Study met 70-day benchmark |
| 12/WA/0230 | Radiotherapy after Oesophageal Cancer Stenting Study | 04/11/2015 | | n/a | 70-day benchmark not yet expired |
| 13/LO/1227 | A Multicenter, Randomized, DoubleBlind, PlaceboControlled, Phase III Study of ARN509 in Men with NonMetastatic (M0) CastrationResistant Prostate Cancer | 16/04/2015 | | No | Eleven patients have been identified, but all were screening failures. Screening process is long as it requires 3 PSA rises before patients meet the eligibility criteria. Study target is only 5 patients over 3.5 years so study team was not envisaging consenting the first patient within 70 days. |
| 14/ES/1064 | A randomized phase II/III study to assess the efficacy of trametinib (GSK 1120212) in patients with recurrent or progressive lowgrade serous ovarian cancer or peritoneal cancer (GOG0281) | 10/10/2015 | | No | Sponsor delayed site activation as they wanted to activate all sites globally at the same time; there were global delays due to additional approvals required by the sponsor in the USA. |

| | | | | | |
|---|---|---|---|---|---|
| 14/YH/1108 | A RANDOMIZED PHASE III TRIAL COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION IN PATIENTS WITH LOW-RISK EARLY-STAGE CERVICAL CANCER | 12/10/2015 | | No | Rare disease. |
| 14/YH/1234 | A phase III, doubleblind, randomised study to assess the efficacy and safety of AZD9291 versus a standard of care Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor as firstline treatment in patients with (...) NonSmall Cell Lung Cancer | 10/04/2015 | | No | Sponsor delay with green light and in providing imaging equipment / access to IWRS system needed to conduct the study. |
| 15/LO/0016 | A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative (?) | 24/07/2015 | | No | Sponsor delays in lab kit being shipped to site which postponed activation until. One patient was eligible but declined to take part. Furthermore, recruitment closed early nationally as achieved global target sooner than anticipated. |
| 15/LO/0273 | Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study Evaluating Safety and Efficacy of the Addition of Veliparib Plus Carboplatin Versus the Addition of Carboplatin to Standard Neoadjuvant Chemotherapy Versus Standard Neoadjuvant Chemotherapy in Subjects with Early Stage Triple Negative Breast Cancer (TNBC) | 12/08/2015 | | No | Neoadjuvant triple negative - rare disease. |
| 15/LO/0571 | A phase II study of alternating eribulin and hormonal therapy in pre-treated ER+ve breast cancer (ALERT) | 08/07/2015 | | No | Delays from the UKCRN in adopting the study onto the portfolio. All site documents in place from day 15 onwards. |
| 15/LO/0691 | An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic (Sq) (NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment of Stage IIIb/IV SqNSCLC | 21/08/2015 | | No | This is a rare disease group by virtue of the criteria - must be 3rd line treatment and hence very few patients. |
| 15/SC/0003 | An Open-Label, Multicenter, Phase 1/2 Study of E7438 (EZH2 Histone Methyl Transferase [HMT] inhibitor) as a Single Agent in Subjects With Advanced Solid Tumors or With B cell Lymphomas | 26/10/2015 | | n/a | 70-day benchmark not yet expired |
| 14/EM/1059 | A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura | 05/02/2015 | 01/10/2015 | No | Rare disease. |
| 14/LO/0673 | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of GS 1101 (CAL-101) in Combination with Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukemia. | 13/02/2015 | 21/07/2015 | No | Rare disease. |
| 13/SC/0157 | ROMAZA: Phase I trial of combination therapy with romidepsin and azacitidine in patients with newly diagnosed, relapsed or refractory Acute Myeloid Leukaemia ineligible for conventional chemotherapy | 16/06/2015 | 12/11/2015 | No | Rare disease. |
| 14/WM/1202 | B0401016: A Phase 1b, Randomized, Double-Blind (Sponsor Open), Placebo-Controlled Study To Evaluate The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of Pf-04447943, (...) In Subjects With Stable Sickle Cell Disease | 11/06/2015 | 22/10/2015 | No | Very rare disease "less than 2.5 in 10,000 people in Europe". |
| 15/LO/0863 | AG348-C-003: A Phase 2, Open Label, Randomized, Dose Ranging, Safety, Efficacy, Pharmacokinetic and Pharmacodynamic Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency. | 14/08/2015 | 25/11/2015 | No | Very rare disease, 1:20 000. |
| 15/WM/0009 | A Phase 3, Randomised, Controlled, Openlabel Study of VELCADE (Bortezomib MelphalanPrednisone (VMP) Compared to Daratumumab in Combination with VMP (DVMP) in Subjects with Previously Untreated Multiple Myeloma who are Ineligible for Highdose Therapy | 02/07/2015 | 13/10/2015 | No | Rare disease. |
| 14/LO/1834 | A Phase I randomised, placebo-controlled, double-blind, single and multiple ascending dose study of the tolerability and pharmacokinetics of GBT440 in healthy subjects and patients with Sickle Cell Disease | 27/04/2015 | 28/05/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0210 | An exploratory, open-label, multicenter study to evaluate the safety and efficacy of ATIR, donor T-lymphocytes depleted ex vivo of host alloreactive T-cells, in patients with a hematologic malignancy, who received a CD34-selected (..) cell | 13/04/2015 | 30/04/2015 | Yes | Study met 70-day benchmark |
| 13/SC/0309 | A Phase Ib Study of Eltrombopag and Azacitidine in Patients with High Risk Myelodysplastic Syndromes and Related Disorders | 11/08/2015 | | No | Rare disease study. Incidence of Myelodysplastic Syndromes is 4 cases per 100,000 - and this study is looking for high risk so the patient group is even rarer. |
| 13/SC/0583 | MATCHPOINT - MAnagement of Transformed CHronic myeloid leukaemia: POnatinib and INTensive chemotherapy: a dose-finding study. | 26/06/2015 | | No | Very rare disease. |
| 14/EM/1060 | A Phase 3 Open Label Extension Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura | 09/03/2015 | | No | Rare disease condition. We were aware the study would not meet the benchmark prior to opening it but the Sponsor asked us to open this rollover study at the same time as the feeder study. |

| | | | | | |
|---|---|---|---|---|---|
| 15/LO/1087 | An Open-label, Multi-centre Post-marketing Study to Assess the Efficacy and Safety of Voncento? in Subjects with Von Willebrand Disease | 20/08/2015 | | No | Very rare disease. |
| 15/LO/1105 | A Randomized, Single-Blind, Multicenter Phase 2 Study to Evaluate the Activity of 2 Dose Levels of Imetelstat in Subjects with Intermediate-2 or High-Risk Myelofibrosis (MF) Relapsed/Refractory to Janus Kinase (JAK) Inhibitor | 14/08/2015 | | No | Myelofibrosis is a very rare disease. This is an uncommon disease, with an annual incidence of approximately 0.4 cases per 100,000 |
| 14/SC/0263 | AWARE II (AWAreness during REsuscitation) - A Multi-Centre Observational Study of the Relationship between the Quality of Brain Resuscitation, and Consciousness, Neurological, Functional and Cognitive Outcomes following Cardiac Arrest | 29/07/2015 | 19/12/2015 | No | Sponsor delays in organising setup of equipment. |
| 14/LO/2004 | Methylnaltrexone for the Treatment of Opioid Induced Constipation & Gastro-Intestinal Stasis in Intensive Care Patients | 21/07/2015 | 14/09/2015 | Yes | Study met 70-day benchmark |
| 12/EE/0445 | A randomised doubleblind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with anaemia undergoing major open abdominal surgery | 27/10/2015 | 15/12/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1428 | A phase 3 multi-centre double-masked randomised controlled trial of adjunctive intraocular and periocular steroid (triamcinolone acetonide) versus standard treatment in eyes undergoing vitreoretinal surgery for open globe trauma | 06/01/2015 | 21/05/2015 | No | We are only aiming to recruit 5 patients a year due to the very specific eligibility criteria, making this essentially a rare disease. No-one in the UK has yet recruited either - as the study relies on a very specific eye trauma patient coming into A&E and that is both unpredictable and rare. |
| 14/SC/0262 | A Phase IV, prospective, open-label, uncontrolled, European Study in patients with neovascular Age-related macular degeneration (nAMD), evaluating the efficacy and safety of switching From intravitreal Aflibercept to RanIbizumab 0.5mg: SAFARI study | 07/01/2015 | 10/03/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0087 | A Phase I, Storer Design, openlabel, crosssectional, single site trial of ANX776 in healthy volunteers, progressive glaucoma/glaucomasuspect/ ocular hypertensive subjects and nonarteritic anterior ischaemic optic neuropathy subjects | 16/04/2015 | 02/06/2015 | Yes | Study met 70-day benchmark |
| 14/LO/1043 | A Multicentre Phase III Double-masked Randomised Controlled Non-Inferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for Macular Oedema due to Central Retinal Vein Occlusion (CRVO). | 15/12/2015 | | n/a | 70-day benchmark not yet expired |
| 14/WM/0083 | A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in Situ (DCIS) | 06/03/2015 | 06/08/2015 | No | Rare disease. |
| 14/NW/0036 | ESPAC 5 - Four arm, prospective, multicentre, randomised feasibility trial of immediate surgery compared with neoadjuvant chemotherapies and neoadjuvant chemoradiotherapy | 12/03/2015 | 19/06/2015 | No | Borderline resectable pancreatic cancer is a rare disease (1 in 10,000). |
| 13/NE/0196 | Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis | 24/07/2015 | 20/10/2015 | No | Recurrent UTIs in patients who self-catheterise is essentially a rare disease patient group due to how experienced and well-trained our nurse specialists are and this is reflected in the low numbers we anticipated in recruiting. We did identify a suitable patient who agreed to consent in under 70 days, but they were ineligible. |
| 14/SC/0237 | A randomised controlled trial to determine the clinical and cost effectiveness of invasive urodynamic studies for diagnosis and management of bladder outlet obstruction in men in the National Health Service (NHS). | 21/07/2015 | 09/10/2015 | No | Study team was actively screening patients immediately after site initiation visit. Inclusion criteria proved challenging and several tests had to be performed to rule out prostate cancer on each patient which eventually showed they were all ineligible. |
| 11/SW/0248 | Gastric Bypass or adjustable gastric Banding surgery to treat morbid obesity: a multi-centre randomised controlled trial | 16/09/2015 | 08/10/2015 | Yes | Study met 70-day benchmark |
| 15/WS/0037 | A single-arm, post-market study of the Endo GI Reinforced Reload with Tri-Staple Technology | 24/04/2015 | 05/05/2015 | Yes | Study met 70-day benchmark |
| 14/EM/1284 | Neo-AEGIS (NEOadjuvant trial in Adenocarcinoma of the oEsophagus and oesophagoGastric junction International Study): Randomised Clinical Trial of neoadjuvant and adjuvant chemotherapy (Modified MAGIC regimen) vs. (CROSS protocol) (?) | 23/07/2015 | 29/07/2015 | Yes | Study met 70-day benchmark |
| 12/EE/0029 | A 12 week, single centre, open label study to evaluate the effect of fesoterodine flexible dosing regimen on the sexual function of women with overactive bladder. | 22/01/2015 | 07/04/2015 | No | Protocol design required complex and very lengthy interview times with patients - many patients either refused to consent or alternatively withdrew. Also the recruitment process required more time from staff than previously anticipated. |

| | | | | | |
|---|---|---|---|---|---|
| 15/NE/0296 | FIRST-line support for Assistance in Breathing in Children (FIRST-ABC) Feasibility Study: feasibility study for a randomised trial of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) (?) critically ill children | 02/11/2015 | 14/12/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1091 | Magnetic Resonance in Infection Primed Neonatal Encephalopathy and N-acetyl (MARINAC) | 07/10/2015 | 05/11/2015 | Yes | Study met 70-day benchmark |
| 14/SC/1345 | The effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding. | 25/08/2015 | 15/09/2015 | Yes | Study met 70-day benchmark |
| 14/SS/1031 | An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability | 27/07/2015 | 14/08/2015 | Yes | Study met 70-day benchmark |
| 15/LO/1341 | Can ultrasound predict outcome of operative vaginal deliveries for prolonged second stage? | 15/10/2015 | 29/10/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0300 | Development and validation of a non-invasive, wearable sensor for fetal movement. | 13/07/2015 | 23/07/2015 | Yes | Study met 70-day benchmark |
| 14/NW/1506 | BlueWind system safety and performance in treatment of patients diagnosed with overactive bladder (OAB) | 14/07/2015 | 15/07/2015 | Yes | Study met 70-day benchmark |
| 15/WM/0256 | Efficacy & Safety of Nasal Influenza Immunisation in Children - The SNIFFLE-3 study | 09/10/2015 | 19/10/2015 | Yes | Study met 70-day benchmark |
| 15/LO/0287 | Boiled Oral Peanut Immunotherapy for the treatment of Peanut Allergy | 05/05/2015 | 23/06/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2103 | Optimising effectiveness and minimising toxicity of intravenous salbutamol in children with acute asthma | 26/05/2015 | 01/07/2015 | Yes | Study met 70-day benchmark |
| 14/WM/0162 | Barrier Enhancement for Eczema Prevention - BEEP | 16/03/2015 | 01/04/2015 | Yes | Study met 70-day benchmark |
| 14/NW/1354 | Romiplostim in Thrombocytopenic Paediatric Patients with ITP | 22/06/2015 | 07/07/2015 | Yes | Study met 70-day benchmark |
| 13/SW/0300 | XENON AND COOLING THERAPY IN BABIES AT HIGH RISK OF BRAIN INJURY FOLLOWING POOR CONDITION AT BIRTH: RANDOMISED PILOT OUTCOMES STUDY | 08/12/2015 | | n/a | 70-day benchmark not yet expired |
| 15/LO/0227 | The Sono-VE Study: Assessing the acceptability and feasibility of transperineal ultrasound and developing an ultrasound based predictive model for labour outcome; the sonopartogram. | 14/04/2015 | 22/04/2015 | Yes | Study met 70-day benchmark |
| 14/LO/2196 | A phase 2, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the safety and efficacy of OBE001 after oral administration in pregnant women with threatened preterm labour | 15/05/2015 | | No | Site very actively screening - 60 participants to date, but all ineligible for various reasons. CRO aware of difficulties, and is now considering changing eligibility criteria. Other UK sites have declined to participate in the study due to difficulties by sites in finding eligible patients. No sites yet recruited in the UK; only 2 patients recruited study wide. |