<table>
<thead>
<tr>
<th>Research Ethics Committee Reference Number</th>
<th>Name of Trial</th>
<th>Date of Receipt of Valid Research Application</th>
<th>Date of First Patient Recruited</th>
<th>Benchmark Met?</th>
<th>Reason for not meeting benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/WM/1055</td>
<td>A prospective, multicenter, randomized, double blind, placebo-controlled, 2 parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with FOLFIRI to placebo in combination with FOLFIRI</td>
<td>09/03/2015</td>
<td>11/03/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>15/LO/0210</td>
<td>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 hematologic malignancy, who received a CD34-selected (..) cell</td>
<td>13/04/2015</td>
<td>30/04/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/EM/1314</td>
<td>Randomized, blinded, multicenter, Phase 2 Study Comparing Velparib Plus FOLFIRI ± Bevacizumab Versus Placebo Plus FOLFIRI ± Bevacizumab in Previously Untreated Metastatic Colorectal Cancer</td>
<td>17/07/2015</td>
<td>28/08/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/LO/1728</td>
<td>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</td>
<td>03/03/2015</td>
<td>17/04/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/NW/1354</td>
<td>Ramiglumis in Thromboctypenic Paediatric Patients with ITP</td>
<td>22/06/2015</td>
<td>07/07/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/EM/1286</td>
<td>A Randomized, Double-Blind Study of Ruxolitinib or Placebo in Combination With Regorafenib in Subjects With Relapsed or Refractory Metastatic Colorectal Cancer</td>
<td>13/08/2015</td>
<td>30/09/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>12/YH/0504</td>
<td>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.</td>
<td>12/02/2015</td>
<td>31/03/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/SC/0262</td>
<td>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 Anti-Angiopceptor to Ranibizumab 0.5mg: SAFARI study</td>
<td>07/01/2015</td>
<td>10/03/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>13/LO/0326</td>
<td>A RANDOMIZED, PHASE 3 STUDY OF GANETESPIB IN COMBINATION WITH DOCETAXEL VERSUS DOCETAXEL ALONE IN PATIENTS WITH ADVANCED NON-SMALL-CELL LUNG ADENOCARCINOMA</td>
<td>09/01/2015</td>
<td>10/03/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>15/LO/0140</td>
<td>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.</td>
<td>04/06/2015</td>
<td>23/07/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>15/EM/0021</td>
<td>A randomised, double blind, placebo controlled multicenter trial, examining the effect of Natroxx™ on the rates of healing for chronic diabetic foot ulcers</td>
<td>23/07/2015</td>
<td>08/09/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>15/WS/0003</td>
<td>A single-arm, post-market study of the Endo GI Reinforced Reload with Tri-Staple Technology</td>
<td>24/05/2015</td>
<td>05/05/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/SC/0091</td>
<td>Randomized, Doubleblind, Multicenter, Phase 3 Study Comparing Velparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous NonSmall Cell Lung Cancer (NSCLC)</td>
<td>30/10/2014</td>
<td>06/01/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>15/SC/0104</td>
<td>A Randomized, Doubleblind, Phase 3 Study of the IAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas (The JANUS 1 study)</td>
<td>17/11/2014</td>
<td>20/11/2014</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/LO/0143</td>
<td>Measurement of low-energy stimulation in patients with atrial fibrillation</td>
<td>15/06/2015</td>
<td>11/06/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/NW/0002</td>
<td>Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL Hemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery -VICTORY Study</td>
<td>10/12/2014</td>
<td>20/01/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
<tr>
<td>14/LO/1834</td>
<td>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</td>
<td>27/04/2015</td>
<td>28/05/2015</td>
<td>Yes</td>
<td>Study met 70-day benchmark</td>
</tr>
</tbody>
</table>
14/10/1581 A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily versus Raltegravir 400 mg Twice Daily, Each in Combination with TRUVADA

10/11/2014 08/01/2015 Yes Study met 70-day benchmark

13/YH/0317 Current Steering to Optimize Deep Brain Stimulation

02/10/2014 16/10/2014 Yes Study met 70-day benchmark

14/NW/0290 Registry of Deep Brain Stimulation with the VERISE? System: Verise DBS Registry

21/11/2014 21/03/2015 Yes Study met 70-day benchmark

14/YH/1153 An Open-Label, Extension Study of the Effects of Leuco-methylthioninium bi (hydromethanesulfonate) in Subjects with Alzheimer's Disease or Behavioral Variant Frontotemporal Dementia

18/11/2014 08/01/2015 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

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

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/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

14/EE/0086 Neuromuscular Electrical Stimulation (NMES) in Patients with Intermittent Claudication

29/10/2014 09/12/2014 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

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

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

14/EE/0193 Adjuvant benefit of Neuromuscular Electrical Stimulation (NMES) in Supervised Exercise in Patients with Intermittent Claudication

20/10/2014 08/12/2014 Yes Study met 70-day benchmark

13/LO/0132 Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial

01/10/2014 09/12/2014 Yes Study met 70-day benchmark

14/LO/1197 Phase Ib open label study to assess the safety, pharmacokinetics and clinical activity of Acelarin (NUC-1031) given on days 1 & 8 with carboplatin on day 1, every three weeks for 6 cycles in participants diagnosed with recurrent ovarian cancer.

30/10/2014 27/11/2014 Yes Study met 70-day benchmark

13/LO/1775 The PRAETORIAN Trial: A prospective, randomised comparison of subcutaneous and transvenous implantable cardioverter defibrillator therapy

26/11/2014 08/12/2014 Yes Study met 70-day benchmark

13/LO/1463 An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease

23/10/2014 22/12/2014 Yes Study met 70-day benchmark

12/WM/0199 A pragmatic randomised controlled trial assessing the impact of a low calorie Cambridge based diet programme (CDBP) on weight loss in obese patients with Type 2 diabetes mellitus treated with insulin

15/10/2014 04/11/2014 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/LO/1727 Diffusion tensor imaging (DTI tractography) in the prostate: Roadmapping the neurovascular bundle prior to radical prostatectomy.

24/11/2014 26/01/2015 Yes Study met 70-day benchmark

14/WS/1096 Uncovering obesity and diabetes related complex metabolic dysregulation associated to endometrial cancer

19/11/2014 15/01/2015 Yes Study met 70-day benchmark

13/LO/1595 Cognitive behavioural therapy vs standardised medical care for adults with Dissociative nonEpileptic Seizures: A multicentre randomised controlled trial.

31/10/2014 03/12/2014 Yes Study met 70-day benchmark

15/LO/0976 Left Atrial Appendage Occlusion Study III

09/09/2015 10/09/2015 Yes Study met 70-day benchmark

14/LO/2060 A PROSPECTIVE MULTICENTRE STUDY OF EFFECTIVENESS OF RIPPLE MAPPING FOR ATRIAL TACHYCARDIA ABLATION

15/03/2015 02/03/2015 Yes Study met 70-day benchmark

12/10/1177 Streamlining Staging of Lung Cancer with Whole Body MRI

27/10/2014 08/12/2014 Yes Study met 70-day benchmark

12/YH/0182 Hyaluronic Acid Binding Sperm Selection - HABSelect

17/09/2014 12/11/2014 Yes Study met 70-day benchmark

14/LO/0157 Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration in Cardiac arrest

27/11/2014 26/12/2014 Yes Study met 70-day benchmark
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

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

EVALUATION OF SORAFENIB in combination with local microtherapy guided by gDiBO/DTPA enhanced MRI in patients with inoperable hepatocellular carcinoma 16/02/2015 01/04/2015 Yes Study met 70-day benchmark

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

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

Development and validation of a non-invasive, wearable sensor for fetal movement. 13/07/2015 23/07/2015 Yes Study met 70-day benchmark

CUT*MIVHER 001 - A randomized phase II/III 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

Intranasal diagnostics in food allergy (INDY): a feasibility study 17/09/2014 17/09/2014 Yes Study met 70-day benchmark

Incentive in Diabetic Eye Assessment by Screening (IDEAS) Trial 12/03/2015 19/03/2015 Yes Study met 70-day benchmark

The effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding. 21/04/2015 21/04/2015 Yes Study met 70-day benchmark

Bypass vs. Angioplasty in Severe Ischaemia of the Leg: Multicentre randomised controlled trial to compare the clinical and costeffectiveness of a 2vein bypass first? with a /best endovascular first/ revascularisation strategy 08/12/2014 31/01/2015 Yes Study met 70-day benchmark

Treatment of Advanced Glaucoma Study (TAGS): A multicentre randomised controlled trial comparing primary medical treatment with primary augmented trabeculectomy for people with newly diagnosed advanced glaucoma 11/09/2014 03/11/2014 Yes Study met 70-day benchmark

Safety of Nasal Influenza Immunisation in Egg Allergic Children The SNIFFLE 2 study 02/10/2014 02/10/2014 Yes Study met 70-day benchmark

The CNS Integrase Inhibitor Study 12/06/2015 14/07/2015 Yes Study met 70-day benchmark

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

Molecular genetics of adverse drug reactions: from candidate genes to genome wide association studies. 31/10/2014 02/12/2014 Yes Study met 70-day benchmark

The ACORN: study: Coping and Relaxation in Pregnancy 04/11/2014 41976 Yes Study met 70-day benchmark

Methylaltrexone for the Treatment of Opioid Induced Constipation & Gastro-Intestinal Stasis in Intensive Care Patients 21/07/2015 24/07/2015 Yes Study met 70-day benchmark

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 42108 Yes Study met 70-day benchmark

The role of intrinsic cardiac autonomic nervous system in human arrhythmogenesis 16/03/2015 42115 Yes Study met 70-day benchmark

Barrier Enhancement for Eczema Prevention - BEEP 16/02/2015 01/04/2015 Yes Study met 70-day benchmark

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

Neo-AEGIS (NEoadjuvant trial in Adenocarcinoma of the oEsophagus) and/or metastatic Renal Cancer 23/07/2015 29/07/2015 Yes Study met 70-day benchmark

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

A Phase Ia clinical trial to assess the safety and immunogenicity of MVA-EBOZ alone and a heterologous prime-boost immunisation with ChAd3-EBOZ and MVA EBOZ in healthy UK volunteers 21/05/2015 15/06/2015 Yes Study met 70-day benchmark

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
15/10/0813  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

15/10/1060  Assessment of digestion and metabolism following altered macronutrient intake  29/07/2015  17/08/2015  Yes  Study met 70-day benchmark

15/H0333  Preoperative Pocket Echocardiography Trial  16/07/2015  31/07/2015  Yes  Study met 70-day benchmark

15/10/0287  Boiled Oral Peanut Immunotherapy for the treatment of Peanut Allergy  03/05/2015  23/06/2015  Yes  Study met 70-day benchmark

14/10/2103  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

15/10/0087  A Phase I, Storer Design, open-label, cross-sectional, single site trial of ANK776 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

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  Rare disease.

14/WM/0170  A Phase 3, Randomized Study To Evaluate the Efficacy of Momelotinib versus Best Available Therapy in Anemic or Thrombocytopenic Subjects with Primary Myelofibrosis, Post-polycythemia Vera Myelofibrosis, Myelofibrosis, a rare disease.  14/10/2014  15/02/2015  No  Myelofibrosis is a rare disease.

13/10/1227  A Multicenter, Randomized, DoubleBlind, PlaceboControlled, Phase II Study of ARN509 in Men with NonMetastatic (M0) CastrationResistant Prostate Cancer  16/04/2015  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.

14/10/0673  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 Leukaemia,  13/02/2015  04/08/2015  No  Rare disease.

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 due to patient data being sent offsite.


14/YH/1234  A phase III, doubleblind, randomised study to assess the efficacy and safety of AZD9391 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  Sponsor delay with green light and in providing imaging equipment / access to IWRS system needed to conduct the study.

14/WS/1105  REVEAL 101MS408 Multicenter study of Natalizumab v Fingolimod in MS  26/03/2015  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.

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  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  Rare disease.

14/10/0102  A First Time in Human, Double Blind, Randomised, Placebo Controlled Phase I Study to Investigate the Safety, Tolerability and Pharmacokinetics of Single and Multiple Ascending Intravenous Doses of SNF472 in Healthy Male Volunteers  15/10/2014  03/02/2015  No  Study opened to recruitment but no eligible patients consented.

14/10/0865  A Phase 2, Multi-Center, Randomised, Double-Blind, Ascending Dose, Placebo-Controlled Clinical Study to Assess the Safety and Efficacy of Fostamatinib in the Treatment of IgA Nephropathy  07/11/2014  Initial NHS permission excluded use of tissue bank to store patient samples. Study team decided to wait until full approval was in place before starting to recruit. Several patients have been approached but declined to take part.

14/10/1994  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  Sponsor took 36 days from R&D approval to issue greenlight - SIV was on 24th July. Site started to recruit immediately but had difficulties in finding potential patients meeting all the criteria. The first patient has been consented and screened on the 14th of September. The second patient consented and was screened the 19th of October, we are now going through the eligibility criteria.
14/NE/1072  A PHASE II RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED BRONCHOSCOPY STUDY TO EVALUATE THE EFFECTS OF LEBRINULMAB ON AIRWAY EOSINOPHILIC INFLAMMATION IN PATIENTS WITH UNCONTROLLED ASTHMA ON INHALED CORTICOSTEROIDS AND A SECOND CONTROLLER MEDICATION  16/01/2015  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 ineligible or declined.

14/NM/1202  B0401016: A Phase II, Randomized, Double-Blind (Sponsor Open), Placebo-Controlled Study To Evaluate The Safety, Tolerability, Pharmacokinetics, And Pharmacodynamics Of PK 0444794A. (…) In Subjects With Stable Sickle Cell Disease  11/06/2015  Rare disease.

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  Site has been very actively screening - 60 participants to date, but all ineligible for various reasons but mainly the requirement of gestational week between 34 and 36. Sponsor appreciates difficulties to find patients, and is now considering lowering requirement to 32 weeks of gestation. Other UK sites have declined to participate in the study due to difficulties by other sites in finding eligible patients. No sites have yet recruited in the UK; only 2 patients recruited study wide.

12/EE/0230  RITAZAREM: Rituximab vasculitis maintenance study - An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCA-associated 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.

13/WA/0117  A randomised phase II trial of Olaparib maintenance versus placebo monoetherapy in patients with non-small cell lung cancer  06/10/2014  16/12/2014  No  Sponsor delays in site activation. Site still managed to quickly recruit first patient 4 days after sponsor green light. Only missed the benchmark by 1 day.

14/EE/0192  Neuromuscular Electrical Stimulation (NMES) in patients with critical limb ischaemia  16/06/2015  Within the last 2 months the study team identified 3 suitable patients. The first patient did not respond to the invitation. The second and third patients delayed screening visits due to illness or being abroad; when the visit took place their health had deteriorated making them ineligible. Critical limb ischaemia (CLI) is a relatively rare presentation, plus very few patients have no tissue loss (no wounds or ulcers) on their feet - required for the use the foot plate device being studied.

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. There was only one eligible patient found and approached, but patient declined to participate in the study.

12/NE/0343  Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy  01/10/2014  22/09/2015  No  Rare disease study (less than 1 in 2000).

14/NY/0085  Front-Line therapy in CLL: Assessment of Brutinib + Rituximab.  26/09/2014  26/02/2015  No  Very rare disease study (0.6 in 10,000 in males & 0.4 in 10,000 in females).

13/NW/0714  ECASS-4: EXTEND - European Cooperative Acute Stroke Study-4 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/VN/1290  Management of myocardial injury After NonAcute surgEry (MANAGE)  25/03/2015  Study team have screened numerous patients, but they did not meet the inclusion criteria and therefore were not suitable to be recruited to the study. One patient was eligible, but declined to take part.

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  Site has no control over deceased organ allocations and there is no way to predict if and when we will be allocated organs for the study.

15/LO/0571  A phase II study of alternating eribulin and hormonal therapy in pre-treated ER+ve breast cancer (ALERT)  08/07/2015  Delays from the UKCRN in adopting the study onto the portfolio. All site documents in place from day 1 onwards.

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/0871  A randomised controlled trial of a duodenal sleeve bypass device (EndoBarrier) compared with standard medical therapy for the management of obese subjects with type 2 diabetes  12/11/2014  13/02/2015  No  Team started looking for patients immediately after gaining approval and 9 days later the first patient was screened and consented (28/11/14). Seven screening failures over a 2 month period until first successful recruitment on 13/02/15.
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, and due to the personal details required for the questionnaire, many patients either refused to consent or alternatively withdrew.

A phase 3 multi-centre double-masked randomised controlled trial of adjunctive intracutaneous and periocular steroid (triamcinolone acetonide) versus standard treatment in eyes undergoing vitreoretinal surgery for open globe trauma 06/01/2015 21/05/2015 No Very specific eligibility criteria, making this essentially a rare disease. No-one in the UK has yet recruited either - study relies on a very specific eye trauma patient coming into A&E and that is both unpredictable and rare.

Improving the management and control of tuberculosis among hard to reach groups 09/02/2015 21/04/2015 No The first suitable patient was identified 22 days after valid submission of study; eventually declined. Study team approached TB REACH Charity to discuss difficulties with screening. A patient was successfully recruited only 1 day after the benchmark of 70 days.

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.

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 Rare disease.

ESPARC 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).


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 Study team was actively screening patients immediately after site initiation visit. Inclusion criteria proved challenging.

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 not yet expired 70-day benchmark not yet expired

A Randomized, Single-Blind, Multicenter Phase 2 Study to Evaluate the Activity of 2 Dose Levels of Imetelstast in Subjects with Intermediate-2 or High-Risk Myelofibrosis (MF) Relapsed/Refractory to Janus Kinase (JAK) Inhibitor 14/08/2015 not yet expired 70-day benchmark not yet expired

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 not yet expired 70-day benchmark not yet expired

A Randomized, Open Label, Multicenter, Phase 2 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator’s Choice of Standard Chemotherapy (T) or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (...) 13/08/2015 not yet expired 70-day benchmark not yet expired

An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic (Sqs) (NSCLC) who Have Received at Least Two Prior Systemic Regimens for the Treatment of Stage IIIb/IV Squamous NSCLC. 21/08/2015 not yet expired 70-day benchmark not yet expired

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 not yet expired 70-day benchmark not yet expired

A 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 (...) Early Stage TNBC 12/08/2015 not yet expired 70-day benchmark not yet expired

HALT-IT - Tranexamic acid for the treatment of gastrointestinal bleeding: an international randomised, double blind placebo controlled trial 09/08/2015 not yet expired 70-day benchmark not yet expired

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 not yet expired 70-day benchmark not yet expired

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 not yet expired 70-day benchmark not yet expired
<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>Date</th>
<th>Status</th>
<th>Expiration Date</th>
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<tr>
<td>13/LO/1618</td>
<td>A Multicenter, Long-term Extension Study to Further Evaluate the Safety and Tolerability of Telotristat Eliprate (LX1606)</td>
<td>04/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<tr>
<td>15/SC/0165</td>
<td>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</td>
<td>24/09/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<tr>
<td>15/LD/0016</td>
<td>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 (7)</td>
<td>24/07/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15MA2807</td>
<td>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</td>
<td>14/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>14/JS/1031</td>
<td>An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability</td>
<td>27/07/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/LD/0153</td>
<td>NACAH - The Mechanism of Action of N-AcetylCysteine for Reducing the Risk of Infection in Alcoholic Hepatitis</td>
<td>18/09/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/LD/0620</td>
<td>Owing of Electrical Stimulation in Venous Insufficiency (DESIVI)</td>
<td>10/09/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/NE/0196</td>
<td>Antibiotic Treatment for Intermittent Bladder Catheterisation: A Randomised Controlled Trial of Once Daily Prophylaxis</td>
<td>24/07/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>14/LD/1291</td>
<td>A phase II randomised study evaluating the biological and clinical effects of the combination of palbociclib with letrozole as neoadjuvant therapy in post-menopausal women with ER+ primary breast cancer</td>
<td>18/09/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/SC/0267</td>
<td>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</td>
<td>30/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>14/SC/0263</td>
<td>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</td>
<td>29/07/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/LD/1011</td>
<td>A Feasibility randomised controlled trial: Effects of oral sodium bicarbonate supplementation in patients on haemodialysis</td>
<td>11/09/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/SC/0309</td>
<td>A Phase Ib Study of Eltrombopag and Azacitidine in Patients with High Risk Myelodysplastic Syndromes and Related Disorders</td>
<td>11/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>14/LO/0612</td>
<td>Care of Late Stage Parkinsonism</td>
<td>12/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/LD/1087</td>
<td>An Open-label, Multi-centre Post-marketing Study to Assess the Efficacy and Safety of Vonconexo® in Subjects with Von Willebrand Disease</td>
<td>20/08/2015</td>
<td>not yet expired</td>
<td>70-day benchmark not yet expired</td>
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<td>15/LD/0743</td>
<td>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</td>
<td>25/08/2015</td>
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