| Research Ethics Committee Reference Number | Full Name of Trial | Date of Receipt of Valid Research Application | Date of First Patient Recruited | Reasons for not achieving the 70 day target from receipt of valid research application to 1st patient recruited | | | | | | | | | | Comments | Reasons for delay correspond to: |
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| | | | | A - Permissions delayed/denied | B - Suspended by sponsor | C - Closed by sponsor | D - Sponsor Delays | E - Staff availability issues | F - No patients seen | G - No patients consented | H - Contracting delays | I - Rare diseases | J - Other | | |
| 13/LO/1081 | PROSPER: A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients With Nonmetastatic Castration-Resistant Prostate Cancer | 18/07/2014 | N/A | Y | | | | | | Y | | | | BSUH was unable to be opened as a site until 1/9/14 due to unsigned paperwork required by Sponsor. Study was closed to recruitment on May 29th 2015. There were 6 screen failures and 4 patients declined. | NHS Provider |
| 11/AL/0081 | SAPROCAN: Saracatinib (AZD0530) and docetaxel in metastatic, castraterefractory prostate cancer: a phase I/randomised phase II study by the UK NCRI Prostate Clinical Studies Group | 18/07/2014 | 05/08/2014 | | | | | | | | | | | 70 day target met | Neither |
| 13/NE/0126 | An exploratory, randomised, double-blind, controlled study to assess the effect of an Amino Acid Based Formula with a synbiotic blend on gut microbiota and stool characteristics in infants with suspected gastrointestinal Non IgE mediated cow's milk allergy (CMA). | 20/06/2014 | 14/08/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/SW/0079 | A Prospective, Randomized Evaluation of the TriGuard™ HDH Embolic DEFLECTion Device during Transcatheter Aortic Valve Implantation | 09/07/2014 | 17/07/2014 | | | | | | | | | | | 70 day target met. | Neither |
| 13/LO/0451 | The United Kingdom Transcatheter Aortic Valve Implantation (UK TAVI) Trial. A multi-centre randomised controlled trial to assess the clinical effectiveness and cost-utility of TAVI, compared with conventional surgical aortic valve replacement, in patients with severe symptomatic aortic stenosis at intermediate or high operative risk. | 01/07/2014 | 17/10/2014 | | | | Y | | | | | | Y | BSUH only had clearance to start recruiting on 8/10/14, which was after the FPR target date. Delay caused by initial 'test' echo being rejected. | Sponsor |
| 10/H0802/13 | The Hypertension Optimal Treatment in Children with Chronic Kidney Disease study: The HOT-KIDS study- A randomised trial to compare effects of aggressive versus standard targets in blood pressure on target organ damage in children with CKD. | 31/07/2014 | N/A | | | | Y | | | Y | | | Y | Laboratory manual required clarification. Delays in response from Evelina Childrens Hospital regarding use of their equipment at BSUH. As at 30/6/15, only one eligible patient passed screening-being reviewed by Evelina Children's Hospital for possible recruitment. Recruitment visit booked for 28.7.15 | Sponsor |
| 10/H0706/65 | A phase III trial comparing standard versus novel CRT as preoperative treatment for MRI defined locally advanced rectal cancer. | 14/08/2014 | 30/04/2015 | | | | | | | Y | | | | Difficult to recruit to. Patients that were initially eligible, subsequently failed screening as they had co-morbidities that precluded randomising them to potentially receive Irinotecan. First patient randomised 30/4/15, second patient in screening | Neither |
| 10/H0715/48 | A Randomised Multicentre Accelerated Radiotherapy Study of Dose Escalated Intensity Modulated Radiotherapy vs Standard Dose Intensity Modulated Radiotherapy in Patients Receiving Treatment for Locally Advanced Laryngeal and Hypopharyngeal Cancers. | 14/08/2014 | 24/09/2014 | | | | | | | | | | | 70 day target met | Neither |

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| 14/EM/0129 | A PHASE 2/3, MULTI-CENTRE, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED (PART A) AND DOUBLE-BLIND, DOUBLE-DUMMY, ACTIVE-CONTROLLED (PART B), PARALLEL GROUP STUDY TO EVALUATE THE EFFICACY AND SAFETY OF RPC1063 ADMINISTERED ORALLY TO RELAPSING MULTIPLE SCLEROSIS PATIENTS | 06/08/2014 | 13/01/2015 | | | | Y | | | Y | | | | Sponsor delays in staff training needed to carry out all the screening assessments. Final training was given on 6/10/14, only 9 days before the FPR target date. 1 patient recruited as at 30 June 2015. | Sponsor |
| 14/WS/0004 | Open-Label Extension Study of EFC12492, R727-CL-1112, EFC12732, & LTS11717 Studies to Assess the Long-Term Safety and Efficacy of Alirocumab in Patients with Heterozygous Familial Hypercholesterolmia | 12/08/2014 | 30/09/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/EE/1016 | A STUDY TO DETERMINE THE ACCURACY OF ZERO-FLUX AND INGESTIBLE THERMOMETERS IN THE PERIOPERATIVE SETTING | 22/08/2014 | 24/09/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/LO/0892 | A Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents | 17/09/2014 | 20/05/2015 | | | | | | | Y | | | | This has proved to be a difficult study to recruit to. As at the end of June 2015, there had been 2 screen failures and 1 patient declined. First patient consented 20/5/15 | Neither |
| 14/LO/0121 | A Phase II, Double Blind, Randomized, Placebo-Controlled Study of the AKT Inhibitor AZD5363 in Combination With Paclitaxel in Triple-Negative Advanced or Metastatic Breast Cancer | 22/09/2014 | 29/09/2014 | | | | | | | | | | | 70 day target met | Neither |
| 13/LO/1595 | COgnitive behavioural therapy vs standardised medical care for adults with Dissociative non-Epileptic Seizures: A multi-centre randomised controlled trial (CODES). | 17/10/2014 | 12/11/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/LO/1381 | Reformulated raltegravir q.d. (1200 mg) versus raltegravir b.i.d. (400 mg) in ART-naïve pts (ONCE) | 22/10/2014 | 13/11/2014 | | | | | | | | | | | 70 day target met. Fully recruited target of 5 as at 30 June 2015. | Neither |
| 14/ES/0072 | How can we optimise inhaled beta2 agonist dose as 'reliever' medicine for wheezy pre-school children. | 15/10/2014 | 13/03/2015 | | | | | | | Y | | | | As at end of June there were >10 screened, but most ineligible or declined. First patient recruited 13.3.15 | Neither |
| 13/LO/0699 | Evaluating the effects of novel GLP-1 analogue, liraglutide, in patients with Alziemer's disease (ELAD study) | 30/10/2014 | 24/03/2015 | | | | | Y | Y | | | | | Difficult to find patients with early AD.<br>PI on extended leave Dec14/Jan15 | NHS Provider |
| 13/YH/0147 | A randomized, Open Label, Multi-Centre, Controlled Study to Assess Safety and efficacy of ELAD in subjects with Acute Alcoholic Hepatitis (AAH) Who have failed Steroid Therapy (incorporating VTI-210E as a follow up registry) | 12/11/2014 | N/A | | | | | | | Y | | | | Difficult recruitment criteria. Patients not eligible | Neither |
| 14/LO/1513 | A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir boosted Atazanavir plus Abacavir/Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR ≥70 mL/min | 23/10/2014 | 05/02/2015 | | | | Y | | | Y | | | | Memo dated 20/11/14 refers to sponsor delay due to drug supply. First patient screened 5/1/2015 but failed screen on viral load. FPR 5.2.15. | Sponsor |

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| 14/WM/0083 | A Phase III Trial of Surgery versus Active Monitoring for Low Risk Ductal Carcinoma in Situ (DCIS) (LORIS) | 01/10/2014 | N/A | Y | | | Y | | | Y | Y | | | Site activation delayed post-SIV as no contract was in place. Once this was resolved, the Sponsor issued an amendment, so recruitment could not commence until the amendment was processed and given all relevant approvals. Amendment approved 6th Jan 2015. As at end of June 2015 there were 2 screen fails and 2 patients in screening. | Both |
| 11/NW/0548 | RIAltO: A Randomised Investigation of Alternative Ofatumumab-containing regimens in less fit patients with CLL | 13/10/2014 | N/A | | | | | | | Y | | | | Every effort has been made to recruit to this study. 7 patients screened in total (not eligible), 4 patients in pipeline but study on hold due to drug supply issues. These issues arose after the FPR date, so did not affect the target not being achieved. | Neither |
| 12/LO/1109 | A Prospective Randomised Phase III Study of Observation Versus Screening MRI And Pre-Emptive Treatment in Castrate Resistant Prostate Cancer Patients With Spinal Metastasis | 17/10/2014 | 09/12/2014 | | | | | | | Y | | | | 70 day target met | Neither |
| 13/SC/0111 | FOCUS4 – Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme | 24/10/2014 | N/A | Y | | | Y | | | | | | | Delays with sending/completing study documentation meant we were unable to commence recruitment until Jan 2015. Screened many but not recruited. Have reduced target figures and are now going to change method of screening. | Both |
| 14/LO/0298 | A multicenter, Single Arm Study of Enzalutamide in Patients with Progressive Metastatic Castration-Resistant Prostate Cancer Previously Treated With Abiraterone Acetate. | 30/10/2014 | 25/11/2014 | | | | | | | | | | | 70 day target met. | Neither |
| 14/LO/1052 | A Phase 2, Randomized, Open-Label, Parallel Group Study Evaluating the Safety andEfficacy of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, forPatients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant AndrogenDeprivation Therapy With External Beam Radiation Therapy (EBRT) | 18/11/2014 | 06/01/2015 | | | | | | | | | | | 70 day target met | Neither |
| 14/EM/1070 | A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Clinical Study Evaluating the Safety and Efficacy of Icatibant as a Treatment for Angiotensin-Converting Enzyme Inhibitor (ACE-I)-Induced Angioedema in Adults | 22/12/2014 | 10/03/2015 | | | | | | | | | Y | | Rare disease type, but only missed 70 day target by 8 days. | Neither |
| 14/YH/0088 | Phase I study of KHK2823 in Patients with Acute Myeloid Leukaemia or Myelodysplastic Syndrome | 17/12/2014 | 29/04/2015 | | | | | | | | | | Y | The principle reason for lack of recruitment is study design. It is a cohort study, and patient slots have to be reserved for identified patients before consent and screening can occur. We have identified 3 potential patients for this study, the first in January 2015, but due to competing sites and safety issues we were not been given a cohort slot until April 2015. | Sponsor |

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| 13/YH/0394 | Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi)/Angiotensin Receptor Blocker (ARB) withdrawal in adncace renal disease: The STOP-ACEi Trial | 14/10/2014 | 14/11/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/YH/0086 | RESPOND: Repositionable Lotus Valve System-Post Market Evaluation of Real World Clinical Outcomes | 06/10/2014 | 22/10/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/SC/1161 | Prospective, single-arm, Multi-centre, observational registry to Further Validate Safety and Efficacy of the Ultimaster DES system in unselected patients representing everyday clinical practice | 18/12/2014 | 22/12/2014 | | | | | | | | | | | 70 day target met | Neither |
| 14/WM/0013 | A Randomized, Double blind, Placebo-Controlled, 2-Part Study of Orally Administered ALS-008176 to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Dosing and Multiple Ascending Dosing in Infants Hospitalized with Respiratory Syncytial Virus (RSV) Infection. | 19/12/2014 | N/A | | | | Y | | | Y | | | | IMP not received until 7/1/15 (sponsor delay). No eligible patients as at 30/6/15 - nil meeting inclusion criteria | Sponsor |
| 13/LO/1891 | More Response on Cardiac Resynchronization Therapy (CRT) with MultiPoint Pacing (MPP) | 04/11/2014 | 07/01/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/LO/0145 | A multicentre phase III randomised controlled single masked clinical trial to test the clinical efficacy of LightMasks at preventing dark adaptation in the treatment of early diabetic macular oedema (CLEOPATRA) | 09/01/2015 | 25/03/2015 | | | | | Y | | | | | | Research Nurse retired and there has been a delay in recruiting a replacement which has caused delays with recruitment. Missed 70 deadline by 5 days. | NHS Provider |
| 14/LO/0203 | Clinical Efficacy and Mechanistic Evaluation of Aflibercept for Proliferative Diabetic Retinopathy.A Multicentre Phase IIb | 08/01/2015 | 10/06/2015 | | | | | Y | | | | | | Research Nurse retired and there has been a delay in recruiting a replacement which has caused delays with recruitment | NHS Provider |
| 12/NW/0361 | A pragmatic randomised controlled trial comparing the effectiveness and cost effectiveness of levetiracetam and zonisamide versus standard treatments for epilepsy: a comparison of Standard And New Antiepileptic Drugs (SANAD-II) | 19/01/2015 | 03/03/2015 | | | | | | | | | | | 70 day target met | Neither |
| 14/LO/1443 | A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in End Stage Renal Disease Subjects on Stable Dialysis | 19/01/2015 | N/A | | | | | | | | | | Y | 15 patients approached but all declined. One patient consented 4/3/15, but within days of randomisation the Sponsor said they were not included because they could not get hold of the required dose of the drug. | Sponsor |
| 09/HO709/56 | Plasma Exchange and Glucocorticoid Dosing in the Treatment of Anti-neutrophil Cytlplasm Antibody Associated Vasculitis: an international Randomised Controlled Trial | 13/01/2015 | 26/01/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/NE/0336 | A randomised, placebo controlled trial of extraoesophageal reflux treatment in the management of upper respiratory symptoms. [TOPPITS: Trial of Proton Pump Inhibitors in Throat Symptoms] | 04/02/2015 | 08/04/2015 | | | | | | | | | | | 70 day target met | Neither |
| 14/LO/1435 | A Double-Blind, Randomized, Parallel-Group, Active-Control Study to Compare the Efficacy and Safety of CHS-0214 Versus EnbrelÂ® in Subjects With Rheumatoid Arthritis and Inadequate Response to Treatment With Methotrexate | 12/02/2015 | N/A | | | Y | | | | Y | | | | Closed to recruitment 7/4/15. Closed early by Sponsor as global target met. Closure was 2.5 weeks in advance of 70-day target date. | Sponsor |
| 14/LO/0117 | Ablation Versus Anti-arrhythmic Therapy for Reducing All Hopital Episodes from Recurrent Atrial Fibrilation | 17/02/2015 | 24/04/2015 | | | | | | | | | | | 70 day target met | Neither |

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| 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 | 06/01/2015 | 23/01/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/SC/0638 | Human papillomavirus infection: a randomised controlled trial of Imiquimod cream (5%) versus Podophyllotoxin cream (0.15%), in combination with quadrivalent human papillomavirus or control vaccination in the treatment and prevention of recurrence of anogenital warts (HIPvac Trial) | 20/01/2015 | 06/03/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/YH/0315 | A randomized, parallel group, open-label, multicentre study to investigate the efficacy and safety of oral BAY 85-3934 and active comparator (darbepoetin alfa) in the maintenance treatment of anemia in pre-dialysis subjects with chronic kidney disease on darbepoetin treatment in Europe and Asia Pacific. | 25/02/2015 | N/A | | | | | | | Y | | | | Difficult recruitment criteria. Patients not eligible. Recruitment closed by sponsor 10/6/15. | Neither |
| 13/WA/0004 | Oral steroids for the resolution of otitis media in children study (OSTRICH) | 04/02/2015 | N/A | | | | | | | Y | | | | Difficult study to recruit to. No parent willing to put their child on steroids. All opted for surgery as preferential route. Following talks with main site, PI closed site to recruitment. | Neither |
| 14/LO/1043 | A Multicentre Phase III Doublemasked Randomised Controlled NonInferiority Trial comparing the clinical and cost effectiveness of intravitreal therapy with ranibizumab (Lucentis) vs aflibercept (Eylea) vs bevacizumab (Avastin) for or Macular Oedema due to Central Retinal Vein Occlusion (CRVO). | 30/03/2015 | 22/04/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/LO/1115 | UK Multicentre Open-label Randomised Controlled Trial Of IV Iron Therapy In Incident Haemodialysis Patients | 08/04/2015 | 30/04/2015 | | | | | | | | | | | 70 day target met | Neither |
| 11/SS/0100 | A multicentre randomised trial to establish the effect(s) of routine administration of Fluoxetine in patients with recent stroke | 21/04/2015 | 03/06/2015 | | | | | | | | | | | 70 day target met | Neither |
| 11/NE/0228 | IoN- Is ablative radioidoine Necessary for low risk throid cancer patients | 15/04/2015 | N/A | | | | Y | | | Y | | | | Site activation delayed post-SIV because sponsor required further information | Sponsor |
| 13/LO/1463 | InterAACT- 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. | 23/04/2015 | 06/05/2015 | | | | | | | | | | | 70 day target met | Neither |
| 14/SS/1048 | A Phase 3b, Multi-center, Randomized-withdrawal, Placebo-controlled, Double blind, Parallel-group Trial to Compare the Efficacy and Safety of Tolvaptan (45 to 120 mg/day, Split-dose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease | 01/05/2015 | 26/05/2015 | | | | | | | | | | | 70 day target met | Neither |
| 13/NI/0188 | A single-arm trial to evaluate the effectiveness of PCI of de novo 3-vessel disease applying the SYNTAX Score II with pressure wire functional assessment and IVUS guidance, using an everolimus-eluting stent with biodegradable abluminal coating | 05/05/2015 | 28/05/2015 | | | | | | | | | | | 70 day target met | Neither |