

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:	
				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, castraterrefractory prostate cancer: a phase I/randomised phase II study by the UK NCRJ 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

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								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 Hypercholesterolemia	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															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															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 Alzheimer's disease (ELAD study)	30/10/2014	24/03/2015															Difficult to find patients with early AD. 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															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															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

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											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 and Efficacy of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, for Patients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant Androgen Deprivation 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

13/YH/0394	Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB) withdrawal in advance 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													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													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													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													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 Cyttoplasm 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 Enbrel® in Subjects With Rheumatoid Arthritis and Inadequate Response to Treatment With Methotrexate	12/02/2015	N/A													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 Hospital Episodes from Recurrent Atrial Fibrillation	17/02/2015	24/04/2015													70 day target met	Neither

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															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															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 radioiodine Necessary for low risk thyroid cancer patients	15/04/2015	N/A															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