

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			
14/EM/0032	A 52-week, multicenter, randomized, double-blind study of subcutaneous secukinumab to demonstrate efficacy as assessed by Psoriasis Area and Severity Index at 16 weeks of treatment compared to ustekinumab and to assess long-term safety, tolerability and efficacy in subjects with moderate to severe plaque psoriasis	02/05/2014	N/A			Y									This study was given NHSP on the same day as VRA but was closed by the Sponsor 32 days later as their global recruitment target was met. Every effort was made to recruit, but we were unable to recruit within this short timescale.	Sponsor
14/LO/0440	Prospective Randomised Controlled Trial comparing Monofocal Intraocular Lenses and Limbal Relaxing Incisions with Toric Intraocular Lenses for correcting Astigmatism up to 2.5 Diopters during standard cataract surgery.	03/06/2014	11/06/2014												70 day target met	
13/LO/1720	A Phase 2, Randomized, Double Blind, Placebo Controlled, Multicenter Study of Efficacy and Safety of Enzalutamide in Combination With Exemestane in Patients With Advanced Breast Cancer That Is Estrogen or Progesterone Receptor Positive and HER2 Normal	05/06/2014	-								Y				This was a difficult study to recruit to. Closed to recruitment early on 04/03/2015. We had 5 screen failures and 1 patient who declined to participate.	Neither
14/LO/0083	An open label study examining the efficacy and cardiovascular risk of immediate versus deferred switch from a boosted PI to dolutegravir (DTG) in HIV infected patients with stable virological suppression. NEAT 22 /SSAT 060	02/05/2014	04/07/2014												70 day target met	
14/SC/0225	Gilead 311-1089 Phase 3 randomised open-label switch study to evaluate F/TAF in HIV-1 positive subjects who are virologically suppressed on regimens containing FTC/TAF (GILEAD 1089)	16/06/2014	22/07/2014												70 day target met	
13/NS/0143	Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension-Free Mid-Urethral Slings in the Surgical Management Of Female Stress Urinary Incontinence	13/06/2014	04/09/2014								Y				Every effort was made to achieve the FPR target, with screening at the fortnightly clinic run by the PI starting as soon as the study was approved. Many patients did not consent or were not eligible (NB 8 patients were screened and ineligible before the first patient was recruited). There are only 3 or 4 patients per clinic, and no clinics have been missed by the research nurse team.	Neither
13/LO/1426	An international multicentre open-label comparative therapeutic exploratory trial to investigate the role of a new neonatal formulation of dobutamine in the treatment of haemodynamic insufficiency in the immediate postnatal period.	16/04/2014	16/08/2014				Y								The Sponsor delayed opening BSUH as a site. We were only activated on 1/8/14, 37 days past the FPR target date.	Sponsor
13/YH/0282	ACT-MOVE: ML28641 - Subcutaneous tocilizumab in rheumatoid arthritis	31/03/2014	09/09/2014							Y					Every effort is being made to recruit to this study, but it is a difficult trial to recruit to as the study drug was licensed shortly after the study opened, and so is available on prescription without the need to be a research participant.	Neither
13/EE/0126	Evaluation of Safety and Efficacy of the BACE™ (Basal Annuloplasty of the Cardia Externally) Device in the Treatment of Functional Mitral Valve Regurgitation [FMR]	04/06/2014	-									Y			No patients recruited by target date, which was expected as this is a rare disease category study.	Neither

14/LO/0081	A Phase IIb, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Multidose, 24-Week Study to Evaluate the Efficacy and Safety of Atacicept in Subjects With Systemic Lupus Erythematosus	23/05/2014	23/03/2015															Difficult study to recruit to. 1st patient recruited 23.3.15. As at the end of March 2015 we had 2 screen failures and 3 patients declined.	Neither
13/LO/1082	Revascularisation or medical therapy in elderly patients with acute anginal syndromes.	06/05/2014	13/06/2014															70 day target met	
12/ES/0023	Does oral sodium bicarbonate therapy improve function and quality of life in older patients with chronic kidney disease and low-grade acidosis?	23/06/2014	21/08/2014															70 day target met	
14/NW/0017	A Prospective, Single-Arm, Clinical-Setting Study to Describe Efficacy, Tolerability and Convenience of Teriflunomide Treatment Using Patient Reported Outcomes (PROs) in Relapsing Multiple Sclerosis (RMS) Patients.	22/04/2014	10/06/2014															70 day target met. BSUH has over-recruited to this study, and is the top recruiting site within Kent, Surrey and Sussex for dementia trials.	
12/SS/0138	REstart or STop Antithrombotics Randomised Trial (RESTART).	14/03/2014	-															Difficulty in finding suitable patients. 3 have been approached but have declined.	Neither
13/LO/0181	Optimisation and Individualisation of HeartSparing Breast Radiotherapy Techniques (The HeartSpare Study): Stage II	27/03/2014	02/06/2014															70 day target met	
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												BSUH was unable to be opened as a site until 1/9/14 due to unsigned paperwork required by Sponsor. As at 31 March 2015 there have been 6 screen failures and 3 patients have declined.	NHS Provider
11/AL/0081	SAPROCAN: Saracatinib (AZD0530) and docetaxel in metastatic, castraterrefactory 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	
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	
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.	
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
13/EM/0476	Post-market registry of patients with de novo lesions in previously untreated vessels that are treated with Absorb Bioresorbable Vascular Scaffold (BVS)	12/05/2014	29/05/2014															70 day target met	
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	Laboratory manual required clarification. Delays in response from Evelina Childrens Hospital regarding use of their equipment at BSUH. As at 31/3/15, only one eligible patient passed screening-being reviewed by Evelina Children's Hospital for possible recruitment.	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	N/A															Every effort is being made to recruit, but no suitable patients have been found. Patients that were initially eligible, subsequently failed screening as they had co-morbidities that precluded randomising them to potentially receive Irinotecan.	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	
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. As at 31 March 2015 there had been 16 screen fails and one patient declined to participate.	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	
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	
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	N/A															This has proved to be a difficult study to recruit to. As at the end of March 2015, there had been 1 screen failure and 1 patient declined.	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	
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	
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. First patient screened 13/11/2014. Study closed to recruitment and fully recruited target of 5	
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 31 March 2015 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								Y		Y					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. We had 1 patient in screening but they were ineligible following data review because the liver was 1 cm too small and the leucocytes were not x3 greater than normal.	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-naive HIV-1 Infected Adults with eGFR \geq 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. FFR 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	-	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, so now open. 1 screen failure in Jan 2015.	Both
11/NW/0548	RIALO: A Randomised Investigation of Alternative Ofatumumab-containing regimens in less fit patients with CLL	13/10/2014												Y	Every effort has been made to recruit to this study, but 4 patients have failed screening and so no patients have been recruited yet.	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		Y				Y							Delays with sending/completing study documentation meant we were unable to commence recruitment until Jan 2015.	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.	
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	
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	-															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 have not been given a cohort slot until April 2015.	Neither
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	
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	
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	
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						Y										IMP not received until 7/1/15 (sponsor delay). No eligible patients as at 31/3/15	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	
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																Research Nurse retired and there has been a delay in recruiting a replacement which has caused delays with recruitment	NHS Provider
14/LO/0203	Clinical Efficacy and Mechanistic Evaluation of Aflibercept for Proliferative Diabetic Retinopathy. A Multicentre Phase IIb	08/01/2015																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	
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																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 Cytoplasm Antibody Associated Vasculitis: an international Randomised Controlled Trial	13/01/2015	26/01/2015															70 day target met	
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																No patients recruited yet. Target date is 15.04.2015	

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											No patients recruited yet. Target date is 23.04.2015
14/LO/0117	Ablation Versus Anti-arrhythmic Therapy for Reducing All Hospital Episodes from Recurrent Atrial Fibrillation	17.02.2015											No patients recruited yet. Target date is 28.04.2015
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	6.1.15	23/01/2015										70 day target met
13/SC/0638	Human papillomavirus infection: a randomised controlled trial of Imiquimod cream (5%) versus Podophylotoxin cream (0.15%), in combination with quadrivalent human papillomavirus or control vaccination in the treatment and prevention of recurrence of anogenital warts (HIPvac Trial)	20.1.2015	06/03/2015										70 day target met
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											No patients recruited yet. Target date is 06.05.2015
13/WA/0004	Oral steroids for the resolution of otitis media in children study (OSTRICH)	04/02/2015											No patients recruited yet. Target date is 15.04.2015
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											No patients recruited yet. Target date is 18.06.2015.