

Research Ethics Committee Reference Number	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/NW/0283	GLOBAL LEADERS: Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current-day intensive dual antiplatelet therapy in all-comers patients undergoing percutaneous coronary intervention with bivalirud	15/08/2013	21/11/2013				Y								Sponsor delays with training for pharmacists	Sponsor
09/MRE00/53	Phase III trial on Concurrent and Adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON Intergroup Trial.	25/10/2013	24/04/2014	Y							Y				Delays caused by EORTC approval. 4 patients screened before first patient was recruited.	Neither
11/NW/0597	An Open-Label, Dose-Escalation, Phase 1/2 Study of the Oral Form of MLN9708, a Next-Generation Proteasome Inhibitor, Administered in Combination With a Standard Care Regimen of Melphalan and Prednisone in Patients With Newly Diagnosed Multiple Myeloma Req	11/11/2013	11/02/2014				Y				Y				Delayed opening after SIV due to delayed IP release. Patient approached within target time but declined.	Sponsor
13/NW/0501	A Phase 3, Randomized, Double-blind, Placebo-controlled Study to compare efficacy and safety of Oral Azacitidine plus best supportive care versus best supportive care as Maintenance Therapy in subjects with Acute Myelogenous Leukemia in complete remission	10/09/2013	05/02/2014				Y					Y			Sponsor delay with contract and costings affected issuing of NHS permission. Delay with lab kits being sent by CRO, which meant they had expired by the time they got to BSUH. Long delays with being reissued. Despite this, BSUH recruited the 1st patient in the UK.	Sponsor
13/SC/0480	A randomized, double-blind, placebo-controlled, cross-over, multi-center study assessing the safety, tolerability and efficacy of SER100 10 mg s.c. twice daily for 2 days in patients with Isolated Systolic Hypertension insufficiently treated with 1-3 anti	15/11/2013	N/A								Y				No patients recruited nationwide. BSUH screened more patients than any other UK site, and received a letter from the Sponsor thanking us for our exceptional recruitment efforts.	Neither
13/LO/0671	A Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Safety and Efficacy of BIIB019, Daclizumab High Yield Process (DAC HYP), Monotherapy in Subjects With Multiple Sclerosis Who Have Completed Study 205MS301.	25/09/2013	29/01/2014										Y		Extension study of 10/H0711/11. Rollover of patients could not take place until after FPR target date, as patients were unable to commence on 13/LO/0671 until they had completed 10/H0711/11. Neither the VRA date nor the date of NHS permission had any bearing on the date the first patient was able to be recruited to this study. The first patient was recruited as soon as they had completed 10/H0711/11.	Neither
13/NW/0560	Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: Solanezumab (LY2062430) Versus Placebo	18/11/2013	10/04/2014								Y				Inclusion/exclusion criteria is very tight. 27 screen failures to get one patient into study.	Neither
12/SS/0109	International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA).	03/10/2013	-	Y			Y								Issues with the patient stress echos & CT imaging, which affected the issuing of IRMER approval. The Sponsor then issued an amendment to broaden the recruitment criteria.	Sponsor
13/NI/0182	A randomised trial of the efficacy of cognitive rehabilitation in Multiple Sclerosis.	12/12/2013	11/02/2014												70 day target met	
12/WA/0230	Radiotherapy after Oesophageal Cancer Stenting Study	02/12/2013	27/02/2014					Y							SIV moved from 28.1.14 to 18.2.14 due to last-minute lack of availability of site staff.	NHS Provider
13/EE/0173	Assessment of the St. Jude Medical Portico™ Re-sheathable Aortic Valve System – Alternative Access (Portico ALT EU)	10/07/2013	N/A	Y			Y								Delayed IRMER approval. Sponsor did not have the equipment to give out to sites. Study abandoned as Sponsor did not have the right size valves.	Both

13/LO/0908	A Phase 2, Single-Arm, Open-Label, Multicenter Study of the Clinical Activity and Safety of Enzalutamide in Patients With Advanced, Androgen Receptor-Positive, Triple-Negative Breast Cancer	16/01/2014	19/03/2014														70 day target met		
12/EE/0445	A randomised double-blind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with anaemia undergoing major open abdominal surgery	20/01/2014	05/06/2014															No potentially eligible patients identified within 70 day target	Neither
13/SC/0016	Randomized open label study of oral versus intravenous antibiotic treatment for bone and joint infections requiring prolonged antibiotic treatment: Multi-centre study	06/02/2014	08/04/2014															70 day target met	
11/WS/0118	Safety and Efficacy assessment of Monoprost® (unpreserved latanoprost) in comparison with Lumigan® 0.01 % and Lumigan® 0.03% UD, in patients with primary open angle glaucoma or ocular hypertension, stabilized by Lumigan® 0.01 % with ocular surface intoler	14/02/2014	23/04/2014															70 day target met	
13/EM/0349	A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer.	10/02/2014	-			Y	Y											4 patients failed screening. Study was suspended while a substantial amendment was processed.	Neither
13/YH/0389	52 WEEK, PHASE 3 DOUBLE-BLIND, RANDOMIZED, PLACEBOCONTROLLED, PARALLEL-GROUP STUDY TO ASSESS THE EFFICACY, SAFETY AND TOLERABILITY OF PF-04950615 IN SUBJECTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.	19/03/2014	N/A															Sponsor delayed site activation. Not activated until 56 days after the SIV, just 4 working days before FPR target date. As at 29/07/2014, 137 sets of patient notes had been screened for eligibility; some patients had declined, most not eligible. BSUH took the decision to close this study early on 30/09/14 .	Sponsor
13/LO/1795	A double-blind, randomized, placebo-controlled, cross-over study to evaluate the clinical efficacy and safety of subcutaneous administration of human plasma-derived C1-esterase inhibitor in the prophylactic treatment of hereditary angioedema	20/03/2014	02/06/2014															Three patients approached within target period, but they declined to participate. BSUH was the first site in Europe to randomise a patient.	Neither
12/LO/1078	A phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse and primary refractory multiple myeloma	25/03/2014	29/05/2014															70 day target met, despite being unable to approach patients until end of May due to IP not being available.	
14/EM/0032	A 52-week, multicenter, randomized, double-blind study of subcutaneoussecukinumab 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															Study closed early (3.6.14) due to global competitive recruitment.	Neither
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	N/A															1 screen failure 17.7.14, and 1 patient declined	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	16/06/2014	22/07/2014													70 day target met	
13/NS/0143	The SIMS trial	13/06/2014	04/09/2014												Y	No suitable patients found within 70 day target	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	Delays from sponsor in granting site activation. Site activation only given on 1/8/14.	Sponsor
13/YH/0282	ACT-MOVE: ML28641 - Subcutaneous tocilizumab in rheumatoid arthritis	31/03/2014	N/A												Y	No potentially eligible patients identified within the 70 day target.	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 13.8.14 target date. Rare disease category study.	Neither
14/LO/0081	A Phase I/II, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Multidose, 24-Week Study to Evaluate the Efficacy and Safety of Ataccept in Subjects With Systemic Lupus Erythematosus	23/05/2014	-												Y	No patients recruited as at 30/9/14, but study team following up potential patients.	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	-												Y	PI is screening but has not been able to identify any eligible patients	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	One patient declined, two screen failures. Delay between NHSP and SIV due to unsigned paperwork required by Sponsor.	NHS Provider
11/AL/0081	SAPROCAN: Saracatinib (AZD0530) and docetaxel in metastatic, castration-refractory 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 symbiotic 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.	

