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		
11/LO/1596	The percutAneous Coronary inTervention prIor to transcatheter aortic VAlve implantaTION (ACTIVATION) trial	25/06/2013	25/02/2014	Y			Y					Y		IRMER approval delay. SIV date delay (more than 6 weeks after NHS permission). Rare disease with only limited clinics at BSUH.	Both
11/NW/0338	A Clinical Outcomes Study to compare the effect of Fluticasone Furorate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardio	05/07/2013	N/A			Y	Y							PIC sites not identified / set up, then study withdrawn by Sponsor	Sponsor
12/EE/0230	An international, open label, randomised controlled trial comparing rituximab with azathioprine as maintenance therapy in relapsing ANCA-associated vasculitis	30/07/2013	-						Y				Y	More than 1 month between NHS permission and SIV dates (1/10/13). No eligible patients identified yet (as at 30.6.14)	Both
12/EE/0274	Tranexamic Acid for the treatment of significant traumatic brain injury: an international, randomised, double blind, placebo controlled trial.	19/06/2013	17/12/2013						Y					First eligible patient seen was recruited	Neither
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH-2	19/06/2013		Y			Y			Y				Pharmacy approval delay and SIV date delay. No suitable patients recruited as at 30.6.14	Both
12/LO/1534	A Multicentre Prospective Open-label Randomised Clinical Trial Comparing the Efficacy of Fixed versus PRN dosing of 700 µg Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) in patients with refractory diabetic macular oedema.	14/06/2013	09/10/2013				Y	Y						Sponsor delays with SIV and 'green light' dates. Delays also due to site personnel and BSUH staff on A/L.	Both
12/LO/1545	Medtronic CoreValve® ADVANCE DA Study	20/06/2013	02/08/2013											70 day target met	
12/SW/0206	Accuracy and cost-effectiveness of dynamic contrast enhanced computed tomography in the characterisation of solitary pulmonary nodules	29/07/2013	22/11/2013				Y							Not opened by sponsor until 25/9/13 as they requested two SIVs (18.7.13 & 25.9.13)	Sponsor
12/SW/0378	Effect of Bivalirudin on Aortic Valve Intervention outcomes 2/3	18/09/2013	06/01/2014									Y	Y	More than 4 weeks between NHS permission and SIV dates. Rare disease with only limited clinics at BSUH	Neither
12/WM/0001	A randomised controlled trial of standard-of-care wound management versus negative pressure wound therapy in the treatment of adult patients with an open fracture of the lower limb	14/06/2013	12/08/2013											70 day target met	
13/EE/0102	PIVOT Neurocognitive function sub-study v1.0	08/05/2013	19/08/2013		Y		Y						Y	Suspension was due to Sponsor-MHRA disagreement over study classification as CTIMP. London scanning unit was not ready.	Both
13/LO/0129	A Phase 4 Cross-Sectional Study of Bone Mineral Density in HIV-1 Infected Subjects	04/06/2013	No patients recruited										Y	PI sickness and short recruitment period so withdrew from study	Neither
13/LO/0314	Predictors of progression from mild cognitive impairment to dementia: brain functional network studies.	21/06/2013	05/08/2013											70 day target met	
13/LO/0572	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Tre	01/07/2013	25/07/2013											70 day target met	
13/LO/0574	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/ Tenofovir Alafenamide Versus Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate in HIV 1 Positive, Antiretroviral Tre	01/07/2013	13/08/2013											70 day target met	

13/LO/0821	A Phase 3 Open-label Safety Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide Single-Tablet Regimen in HIV-1 Positive Patients with Mild to Moderate Renal Impairment	16/07/2013	28/11/2013				Y			Y				Sponsor delayed the SIV. No eligible patients seen within target timeframe.	Sponsor
13/LO/0830	Phase 3 open label study evaluating the efficacy and safety of pegylated interferon lambda-1a, in combination with ribavirin and daclatasvir, for treatment of chronic HCV infection with treatment naïve genotypes 1, 2, 3 or 4 in subjects co-infected with HIV	19/07/2013	30/09/2013	Y						Y				Delayed opening as Sponsor revised the protocol after the VRA was made and REC approval for the protocol was not received until 9/9/13. Despite this, the 1st patient was recruited 3 days after 70 day target. Several patients declined to participate before this.	Sponsor
13/NW/0002	Prospective, randomised, controlled investigation comparing the safety and performance of 032-11 Surgical Haemostat 2g Applicator with FLOSEAL® Haemostatic Matrix as an adjunctive haemostat in cardiac surgery and thoracic aortic surgery	24/06/2013	28/11/2013				Y				Y			Sponsor delays with contract and with staff training. Not open to recruitment until 10/10/13.	Sponsor
13/NW/0316	Risk of Squamous Cell Carcinoma on Skin Areas Treated with Ingenol Mebutate Gel, 0.015% and Imiquimod Cream, 5% A phase 4 trial comparing the cumulative incidence of SCC after treatment with ingenol mebutate and imiquimod for multiple actinic keratoses on Face and Scalp. A Multi-centre, Randomised, Two-arm, Open Label, Active-controlled, Parallel Group, 36-month Trial	06/08/2013	08/11/2013							Y				No eligible patients screened during the target timeframe	Neither
13/SC/0146	A Phase III, Randomised, open label, parallel group, Active-controlled study of an interferon-free regimen of BI 207127 in Combination with Faldaprevir and Ribavirin compared to Telaprevir in combination with pegylated interferon-α and ribavirin in Treatm	02/07/2013	N/A			Y	Y							Drug not available, then the study was cancelled by the Sponsor before opening to recruitment.	Sponsor
13/SC/0279	A Phase 3, Open-Label Study to Evaluate Switching from a TDF-Containing Combination Regimen to a TAF-Containing Combination Single Tablet Regimen (STR) in Virologically Suppressed, HIV1 Positive Subjects.	16/07/2013	14/10/2013							Y	Y			Delayed while awaiting signed CTA, so NHS permission not given until 24/9/13. Patients declined before 1st patient recruited.	Neither
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. Automatic rollover of patients did not take place until after target date, as patients were unable to commence on 13/LO/0671 until they had completed 10/H0711/11. This was always known to be the case, and the VRA was made too early for there to be any possibility of achieving the target. The date of NHS permission had no bearing on this.	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 PorticoTM 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 they did not have the right size valves. BSUH doing PORTICO1 instead once amendment has gone through.	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						Y					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				3 patients failed screening. Study on hold while a substantial amendment is 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				Y			Y				Sponsor delayed opening post-SIV (27/3/14). As at 30.6.14, 76 sets of patient notes have been screened for eligibility; some patients have declined, most not eligible.	Neither

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							Y				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			Y								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												No patients recruited yet. 70 day target 14/08/2014	
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												No patients recruited yet. 70 day target is 25.8.14	
13/NS/0143	The SIMS trial	13/06/2014												No patients recruited yet. 70 day target is 22.8.14	
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	-				Y				Y		Y	Delays from sponsor in granting site activation and delays with CTA. New Clinical Trial Manager assigned by Sponsor is aware of these delays and is working to resolve issue and hopefully grant site activation before the end of July 2014	Sponsor
13/YH/0282	ACT-MOVE: ML28641 - Subcutaneous tocilizumab in rheumatoid arthritis	31/03/2014							Y					No eligible patients found with 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 yet. 70 day target is 13.8.14	
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	-											No patients recruited yet. 70 day target is 1.8.14	
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	-											No patients recruited yet. 70 day target is 1.9.14	

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	
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	