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		
09/H0718/40	Study on Pharmacokinetics of newly developed Antiretroviral agents in HIV-infected pregNAnt women (PANNA).	07/02/2013	05/09/2013				Y					Y		Delayed due to Sponsor not being ready to set up satellite site. SSI submitted February; SIV not until June. Only 1-2 recruits expected nationwide. No pregnant women available locally within the target timeframe.	Sponsor
10/H1307/99	TRACTISS: A randomized double blind placebo controlled clinical TRial of anti-B-Cell Therapy In patients with primary Sjögren's Syndrome	09/05/2013	31/10/2013							Y				4 patients screened before target date. All failed due to being unable to fulfil a baseline procedure.	Neither
11/AL/0163	PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples	22/04/2013	21/06/2013											70 day target met	
11/LO/0043	Weekly Chemotherapy in Ovarian Cancer v2.0	04/03/2013	19/09/2013				Y							Delayed confirmation from Sponsor due to query about lab accreditations.	Sponsor
11/LO/1570	Cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP) versis gemcitabine, cisplatin and methyl prednisolone (GEM-P) in the first line treatment of T-cell Lymphoma, a multicentre randomise	26/04/2013	N/A	Y						Y				Delayed in obtaining SSA exemption for CISC. No eligible patients seen in target timeframe.	NHS Provider
11/SC/0398	The Contact PVI Study Does assessment of tissue contact during RF ablation using the St. Jude Medical™ Ensite™ Contact™ system increase rates of longterm pulmonary vein isolation? A prospective randomised study.	21/05/2013	-				Y			Y				Sponsor delay in training site staff. No patients recruited yet.	Sponsor
12/LO/0491	Surgical Replacement & Transcatheter Aortic Valve Impantation SURTAVI	11/12/2012	-				Y							Issues with the surgical risk score - sponsor had to complete an amendment so more patients could be recruited.	Sponsor
12/LO/1331	Preoperative treatment of a low haemoglobin in cardiac surgery: pragmatic open-label randomised controlled trial to compare treatment using intravenous iron plus darbepoetin versus standard care.	17/01/2013	18/04/2013	Y						Y				Pharmacy approval delay	NHS Provider
12/LO/1409	A prospective, observational study to examine the effects of ageing on the clinical outcomes of people living with HIV in England and Ireland.	03/05/2013	09/07/2013											70 day target met	
12/LO/1698	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	10/05/2013	25/10/2013				Y							Sponsor delay in supplying drug. Decided not to initate site until August.	Sponsor
12/LO/1717	AN OPEN LABEL RANDOMISED PHASE II STUDY COMPARING AZD2014 VERSUS EVEROLIMUS IN PATIENTS WITH ADVANCED METASTATIC RENAL CANCER AND PROGRESSION ON VEGF TARGETED THERAPY	20/05/2013	04/07/2013											70 day target met	
12/LO/1753	Using expressive writing interventions to promote health in women after birth	03/04/2013	04/04/2014				Y	Y						Study material received late as delayed until Sponsor was able to print it; Research nurse recruited 11/11/13	Both
12/NI/0146	A Phase 3 Randomized, Double-Blind, Placebo-Controlled study of the safety and effectiveness of Immune Globulin Intravenous (Human), 10% solution (IVIG, 10%) for the treatment of mild to moderate Alzheimer's Disease (AD).	14/03/2013	01/05/2013											70 day target met	

12/NW/0105	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Adaptive Design Study of the Efficacy, Safety, and Tolerability of a Single Infusion of MK-3415 (Human Monoclonal Antibody to Clostridium difficile toxin A), MK-6072 (Human Monoclonal Antibody to	22/04/2013	02/07/2013				Y							Following the SIV, there was month's delay in recruitment due to a delay with drug delivery. Despite this, we recruited our 1st patient on day 71, i.e. 1 day past the target date.	Sponsor
12/NW/0214	TAILoR – (TelmisArtan and InsuLin Resistance in HIV): A Dose-Ranging Phase II Randomised Open-Labelled Trial of Telmisartan as a strategy for the Reduction of Insulin Resistance in HIV-Positive Individuals on Combination Antiretroviral Therapy (cART)	10/05/2013	24/10/2013				Y				Y			Delay is providing contract and giving green light to recruit	Sponsor
12/NW/0723	A multi-centre, open-label, long term safety extension of phase II studies ABE4869g and ABE4955g in patients with mild to moderate Alzheimer's Disease.	25/04/2013	04/07/2013											70 day target met	
12/WS/0305	A PROSPECTIVE RANDOMIZED COMPARISON OF THE BIOFREEDOM BIOLIMUS A DRUG COATED STENT VERSUS THE GAZELLE BARE METAL STENT IN PATIENTS AT HIGH RISK FOR BLEEDING	16/04/2013	28/06/2013						Y					1st patient seen was recruited, 3 days past 70 day target	NHS Provider
13/EE/0038	Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial	24/05/2013	10/09/2013							Y				Time lag between NHS permission and SIV dates. No eligible patients were found before the 70 day target.	Neither
13/LO/0033	Genentech GO28509-PEGGY: A PHASE II, randomized STUDY OF paclitaxel with GDC-0941 versus paclitaxel with placebo IN PATIENTS WITH LOCALLY RECURRENT OR METASTATIC BREAST CANCER	18/03/2013	08/10/2013							Y				Several patients failed screening so unable to find eligible patients within target time	Neither
13/LO/0277	The 4 Mountains Test of spatial memory: evaluation of diagnostic sensitivity for mild cognitive impairment due to Alzheimer's disease.	07/05/2013	06/08/2013							Y				No eligible patients screened during the target timeframe	Neither
13/LO/0613	Multimodal imaging of frontal lobe dementias.	20/06/2013	13/08/2013											70 day target met	
13/LO/0621	The 4 Mountains Test of spatial memory for diagnosis of early Alzheimer's disease: evaluation of diagnostic specificity.	07/06/2013	05/08/2013											70 day target met	
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.	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 screened within target timeframe.	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			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/Teno fovir 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 H	19/07/2013	30/09/2013	Y						Y				Delayed opening as REC approval of new protocol 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	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			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	N/A				Y			Y				Delays caused by EORTC approval. 4 patients screened, expect to recruit week commencing 14/4/14.	Sponsor
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							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	-							Y				No eligible patients screened. No patients recruited nationwide. BSUH has screened more patients than any other UK site.	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.	Neither
13/NW/0560	Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: Solanezumab (LY2062430) Versus Placebo	18/11/2013		Y										Delay with R&D set up (Sussex Partnership, not BSUH)	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 IRMER approval. The sponsor had to complete an amendment to be able to approach more patients.	Sponsor
13/NI/0182	A randomised trial of the efficacy of cognitive rehabilitation in Multiple Sclerosis.	12/12/2013		Y										Delay with R&D set up (Sussex Partnership, not BSUH)	Neither

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	-	Y			Y							Delayed IRMER approval. Sponsor did not have the equipment to give out to sites	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	N/A							Y				No eligible patients have been screened	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	N/A											No patients recruited yet. 70 date target 25/04/2014	
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	N/A											No patients recruited yet. 70 day target 21/04/2014	
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											No patients recruited yet. 70 day target 28/05/2014	
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	N/A											No patients recruited yet. 70 day target 29/05/2014	
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	N/A											No patients recruited yet. 70 day target 03/06/2014. Opened to recruitment 14/4/14, but unable to approach patients until end of May due to IP not being available.	Sponsor