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/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				Every effort is going into recruiting to this study, but recruitment is difficult due to the haemoglobin range required, and the short notice given pre-surgery (c.10 days). Research bloods are required at least 10 days before surgery, which means there is often no time for consent. Other Trusts are experiencing the same problem with this study.	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	23/10/2014	Y	Y					Y				This study is only expected to recruit 3 patients over 2 years, which equates to 1 patient every 8 months. It is therefore not surprising that there were no patients recruited within the FPR target timeframe. Every effort is being made to recruit, and the 1st patient was recruited 23/10/14. 3 further patients failed screening; 1 further patient was consented but subsequently failed eligibility due to a liver reading.	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 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							Y				Three patients were 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								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.	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								Y				This is a difficult study to recruit to, and as at December 2014 we have had 3 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	The SIMS trial	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 afer 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 Efficicacy and Safety of Atacicept in Subjects With Systemic Lupus Erythematosus	23/05/2014	-							Y				Difficult study to recruit to. As at December 2014 we have had one screen failure and one patient 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	-						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						Y				BSUH was unable to be opened as a site until 1/9/14 due to unsigned paperwork required by Sponsor. As at 31 December 2014 there have been 5 screen failures and 2 patients have declined.	NHS Provider
11/AL/0081	SAPROCAN: Saracatinib (AZD0530) and docetaxel in metastatic, castraterefractory 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	ABSORB UK Registry - A post-market registry of patients with de novo lesions in previously untreated vessels treated with Absorb 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			Y	Laboratory manual required clarification. Delays in response from Evelina Childrens Hospital regarding use of their equipment at BSUH. As at the end of December 2014, multiple screen failures and 1 eligible patient declined study entry.	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							Y				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 (don't submit in Jan 2015 report)				Y			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 December 2014 there had been 15 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 Hypercholesterolmia	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							Y				One screen failure (5/11/14)	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-naive 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								Y				As at 31/12/14 - 10 screened. 2 were eligible but 1 declined, and 1 got chickenpox so currently unable to participate in study.	Neither
13/LO/0699	Evaluating the effects of novel GLP-1 analogue, liraglutide, in patients with Alziemer's disease (ELAD study)	30/10/2014								Y				Four screen failures as at December 2014. 2 potential screens need PI approval. Still within FPR target timeframe.	
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												No patients recruited yet. 70 day target is 21.01.2015	
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					Y			Y				(Gilead) delayed study activation due to delay with treatment arm drug. Still within 70-day target timeframe.	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.	Both
11/NW/0548	RIAltO: 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								Y				Many patients have been screened but none have been eligible. Screening method being reviewed.	Neither
13/SC/0111	FOCUS4 – Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	24/10/2014		Y			Y							Still within FPR target timeframe. Not yet open to recruitment due to delays with study documentation.	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 andEfficacy of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, forPatients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant AndrogenDeprivation Therapy With External Beam Radiation Therapy (EBRT)	18/11/2014												No patients recruited yet. 70 day target is 27.01.15	
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												No patients recruited yet. 70 day target is 02.03.15	
14/YH/008	Phase I study of KHK2823 in Patients with Acute Myeloid Leukaemia or Myelodysplastic Syndrome	17/12/2014												No patients recruited yet. 70 day target is 25.02.15.	
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			Y				No patients recruited yet; IMP still not received at site as at 31 December 2014. 70 day target is 17.02.15.	Sponsor
13/LO/1891	More Response on Cardiac Resynchronization Therapy (CRT) with MultiPoint Pacing (MPP)	04/11/2014	07/01/2015 (to include in next submission)											Still within FPR target timeframe as at 31 December 2014.	