

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient (days)	Benchmark Met	A - Permissions delayed/ denied B - Suspended by sponsor C - Closed by	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients	H - Contracting delays	I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
15/WA/0189	126958	NHS Permission	Bedside Inotropy - validation of a non- invasive technique to rapidly measure cardiac contractility		08/06/2015	4	Yes									This study has a difficult patient	
10/H0802/46	52863	NHS Permission	Revascularisation for Ischaemic Ventricular Dysfunction (REVIVED)	12/06/2015			No				Υ					population with unfortunately 40-50% of patients dying before they can be approached.	Neither
13/SC/0645	143871	NHS Permission	Pre-eclampsia in Hospital: Early Induction or Expectant Management	18/03/2015	01/07/2015	91	No			Y						Staff capacity issues. First patient recruited 01/07/2015. Delay in Site Initiation Visit by	NHS Provider
14/SC/1223	135378	NHS Permission	A phase II randomised feasibility study of chemoresection and surgical management in low risk non muscle invasive bladder cancer.	22/06/2015	08/02/2016	220	No	,	Y	Υ	Υ					sponsor and issues with NHS Provider Pharmacy. Site activated by sponsor on 21/10/2015. Medical staff capacity and lack of patients seen have impacted on recruitment in Q3 2015/16.	Both
14/SC/0033	146569	NHS Permission	PHASE 3 MULTI CENTER, DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS PHASE 3 MULTI CENTER, DOUBLE	07/07/2015	10/12/2015	148	No	,	Y	Υ						Delay in site activation by sponsor (01/10/2015) disrupted research team capacity plan.	Both
14/SC/0032	142458	NHS Permission	BLIND, RANDOMIZED, PLACEBO CONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF PF 04950615, IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS	07/07/2015	10/12/2015	148	No	`	Y	Υ						Delay in site activation by sponsor (01/10/2015) disrupted research team capacity plan.	Both
14/YH/0085	126738	NHS Permission	FLAIR: Front-Line therapy in CLL: Assessment of Ibrutinib + Rituximab	09/07/2015	19/08/2015	33	Yes										
11/SS/0100	84669	NHS Permission															



**NHS Foundation Trust** 

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient (days)	Benchmark Met	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	Comments	Reasons for delay correspond to:
15/SC/0085	171841	NHS Permission	A feasibility study with a crossover design to assess the diagnostic accuracy of acetic acid targeted biopsies versus non targeted biopsies (current practice) for detection of dysplasia during Barrett's surveillance: the ABBA study.	17/09/2015	07/12/2015	70	No					Υ						Staff capacity issues.	NHS Provider
15/LO/0802	178139	NHS Permission	supplements in children requiring nutritional support - a pilot trial	28/07/2015	12/10/2015	74	No					Υ						Staff capacity issues.	NHS Provider
15/WS/0061	178522		A Randomized, Double-blind, Event-driven, Multicenter Study Comparing the Efficacy and Safety of Rivaroxaban with Placebo for Reducing the Risk of Death, Myocardial Infarction or Stroke in Subjects with Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure	09/09/2015	23/03/2016	176	No							Y				Suitable patients are being screened, however of the few eligible patients seen, the majority of patients have declined to participate.	Neither
13/NS/0155	139913		A multicentre randomised controlled trial comparing laparoscopic supracervical hysterectomy with second generation endometrial ablation for the treatment of heavy menstrual bleeding (HEALTH)	04/11/2015	01/03/2016	117	No						Υ					No eligible patients seen until first patient consented.	Neither
15/LO/1035	164893	NHS Permission	Multinational Abluminal Sirolimus Coated BiOEngineered StenT The MASCOT Post Marketing Registry	18/09/2015	30/10/2015	24	Yes												
15/SC/0448	183584		A randomized, double-blind, placebo- controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care.	12/10/2015	09/12/2015	44	Yes												

27/04/16 2 of 3



NHS Foundation Trust

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient (days)	Benchmark Met	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	Comments	Reasons for delay correspond to:
15/SW/0194	185459	NHS Permission	A randomized, double-blind, placebo- controlled, parallel-group, multicenter, eventdriven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease	12/10/2015	06/01/2016	72	No							Υ				No response from potential participants from invitation letters.	Neither
15/SC/0397	183591	NHS Permission	An evaluation of the tolerance, and acceptability of an amino acid based feed for children	16/12/2015	04/03/2016	49	No						Υ	Υ				Mixture of ineligible patients and patients not wishing to consent to study.	Neither
13/NS/0103	101577	NHS Permission	PREEMPT: Preventing Recurrence of Endometriosis by Means of long acting Protestogen Therapy	19/01/2016			No				Υ		Υ					Site not activated by sponsor until 29/02/2016. Six patients have since been screened, one of whom consented but was subsequently found to be ineligible during the screening laparoscopy.	Neither
14/SC/0171	120104	NHS Permission	recurrence and survival after primary therapy in common nonmetastatic solid tumours.	26/01/2016			Within 70 Days												
15/WA/0106	167739	NHS Permission	PRotective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in OBESE Patients? The PROBESE Randomized Controlled Trial	07/01/2016	01/03/2016	4	Yes												
15/SC/0461	180750	NHS Permission	Bypass surgery in patients with Type 2 diabetes.	01/03/2016	14/03/2016	6	Yes												
11/LO/1261	74423	NHS Permission	Phase III international, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum	19/01/2016			No	Υ				Υ	Υ					Delay in approval by site team due to capacity issues surrounding HRA transition. Subsequently no eligible patients seen since approval; strict inclusion criteria.	NHS Provider

27/04/16 3 of 3