

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:
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.		08/02/2016	231	No				Υ	Υ	Υ					Delay in Site Initiation Visit by 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	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	42348	156	No				Υ	Υ						Delay in site activation by sponsor (01/10/2015) disrupted research team capacity plan.	Both
14/SC/0032	142458	NHS Permission	PHASE 3 MOLTI 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	07/07/2015	10/12/2015	156	No				Y	Y						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	41	Yes												
11/SS/0100	84669	NHS Permission	A multicentre randomised trial to establish the effect(s) of routine administration of Fluoxetine for six months in patients with a recent stroke	29/07/2015	14/09/2015	47	Yes												
15/SC/0085	171841	NHS Permission	A reasibility 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	81	No					Y						Staff capacity issues.	NHS Provider
15/LO/0802	178139	NHS Permission	The effect of standard versus high energy, low volume oral nutritional supplements in children requiring nutritional support - a pilot trial	28/07/2015	12/10/2015	76	No					Υ						Staff capacity issues.	NHS Provider

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15/WS/0061	178522	NHS Permission	A Randomized, Double-billid, 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	196	No							Υ				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	NHS Permission	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	118	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	42	Yes												
15/SC/0448	183584	NHS Permission	A randomized, double-biffid, pracébo- 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	58	Yes												
15/SW/0194	185459		A randomized, double-billind, 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	86	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	79	No						Υ	Υ				Mixture of ineligible patients and patients not wishing to consent to study.	Neither

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13/NS/0103	101577	NHS Permission	PREEMPT: Preventing Recurrence of Endometriosis by Means of long acting Protestogen Therapy	19/01/2016	25/05/2016	127	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	therapy in common nonmetastatic solid tumours.	26/01/2016	25/04/2016	90	No	Y										Delay in approval by site team due to capacity issues surrounding HRA transition and general staff capacity. Site not activated by sponsor until 08/04/2016.	NHS Provider
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	54	Yes												
15/SC/0461	180750	NHS Permission	A pilot study to investigate whether the permeability of the intestinal mucosa is altered after Gastric Bypass surgery in patients with Type 2 diabetes. Phase III international, randomized	01/03/2016	14/03/2016	13	Yes												
11/LO/1261	74423	NHS Permission	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	02/06/2016	135	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
15/EE/0010	138590	NHS Permission	Phase III trial in Intrahepatic Cholestasis of Pregnancy (ICP) to Evaluate ursodeoxycholic acid (UDCA) in improving perinatal outcomes	03/05/2016	10/06/2016	38	Yes												
14/EE/1293	164389	NHS Permission	The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH) Trial: A Randomised Controlled Trial of monofilament versus braided sutures for insufficient cervix.	03/06/2016			Within 70 Days												
15/SC/0257	173423	NHS Permission	Palliative long-term abdominal drains versus repeated drainage in individuals with untreatable ascites due to advanced cirrhosis: a feasibility randomised controlled trial	08/04/2016			No						Υ			Y		Small number of patients required with tight inclusion criteria for this palliative care research project.	Neither

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15/NW/0551	183489	NHS Permission	Improving teenage self-management of asthma: Randomised Controlled Trial		14/04/2016	41	Yes												

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