Western Sussex Hospitals NHS
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 (old metric)	Date Site Invited (new metric)	Date Site Selected (new metric)	HRA Approval Date (new metric)	Date Site Confirmed By Sponsor (new metric)	Date Site Confirmed (new metric)	Date Site Ready to Start (new metric)	Date of First Patient Recruited	Non-Confirmation Status (new metric)	Duration between VRA / Date site selected 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:
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						Y					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-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		58	Yes												
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		86	No								Y				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						Y	Y				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							25/05/2016		127	No				Y		Y					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	A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary 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.	01/03/2016							14/03/2016		13	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							02/06/2016		135	No	Y				Y	Y					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

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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										No						Y					This is an unusual condition and no eligible patients seen to date.	Neither
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							26/08/2016		140	No						Y			Y		The sponsor requested the SSI form be validated prior to all study documentation being ready due to HRA transition.Small number of patients required with tight inclusion criteria for this palliative care research project.	Neither
15/NW/0551	183489	NHS Permission	Improving teenage self-management of asthma: Randomised Controlled Trial	04/03/2016							14/04/2016		41	Yes												
16/EM/0133	184873	HRA Approval	A randomised, double-blind, placebo-controlled multicentre study of secukinumab to evaluate the safety, tolerability and efficacy up to 2 years in patients with active nonradiographic axial spondyloarthritis		09/06/2016	09/06/2016	19/04/2016	29/09/2016	07/10/2016			N/A		No								Y		Y	SIV 13/09/16. Radiology capacity issues. Contract delayed by sponsor.	Both
16/WS/0068	199202	HRA Approval	Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour - QUIDS		19/05/2016	10/08/2016	13/07/2016	27/06/2016	10/08/2016			N/A		No				Y	Y						Amended study documentation presented by sponsor at SIV which necessitated additional communication to resolve agreement to continue.	Both
16/EM/0193	190690	HRA Approval	A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal-GenE trial		09/03/2016	03/06/2016	14/06/2016	04/10/2016	10/10/2016			N/A		No				Y							SIV planned 17/10/16. Sponsor and HRA delays regarding requirement for a material transfer agreement - created significant delays.	Sponsor