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:
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	Y				Sponsor delayed "confirmation of study open to recruitment at site" from NHS Permission date of 20/01/2016, not giving greenlight to open until 29/02/2016. Six patients were screened prior to Q3 2016/17 but all bar one did not wish to consent. One patient provided consent but was subsequently found to be ineligible during the screening laparoscopy.	Sponsor
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			Y							Delay in approval by site team due to capacity issues surrounding HRA transition and general staff capacity. Site activation then delayed by sponsor until 08/04/2016.	Both
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
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					VRA to NHSP time delayed due to sponsor requesting SSI form be validated prior to all study documentation being ready (due to HRA transition and desire to see study processed through NHS Permission route) and also due to requirement for a Licence to Attend for the register involved from the sponsor organisation (sponsor HR delayed confirmation of checks). Small number of patients required with tight inclusion criteria for this palliative care research project.	Sponsor

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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	15/12/2016				No	Y									Y	SIV 13/09/16. Radiology capacity issues and delay in IRMER sign off.	NHS Provider
16/WS/0068	199202	HRA Approval	Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour - QUIDS		19/05/2016	03/10/2016	13/07/2016	27/06/2016	10/08/2016	31/10/2016	02/11/2016		30	Yes											SIV delayed by sponsor. Final protocol presented by sponsor at SIV (03/10/2016) which necessitated additional communication to resolve agreement to continue.	
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	20/10/2016	04/11/2016		154	No				Y						Y	SIV 17/10/16 and greenlight received to recruit on 20/10/16. Sponsor and HRA delays regarding requirement for a material transfer agreement - created significant delays.	Sponsor
17/EM/0005	215706	HRA Approval	A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction		27/10/2016							Site declined to participate	N/A	Site Not Confirmed											Upon review of the protocol, the inclusion criteria for this study was found to be very similar to that of another study which we are about to initiate. We do not have capacity to run both studies at the same time and so it was agreed not to open this study. Site declined 17/11/16.	
16/LO/1822	212944	HRA Approval	A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi- Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFrEF) - VerICiguaT Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA)		11/05/2017	05/10/2016	07/12/2016					Site declined to participate	N/A	Site Not Confirmed											Site declined 06/01/2017 - PI no longer able to act as PI. No other consultant able to take on the role of PI for the duration of the study.	