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/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	Y				This is an unusual condition and no eligible patients seen to date. Q4 16/17 update: two patients who were eligible did not wish to participate in this study.	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
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				Y	SIV 13/09/16. Radiology capacity issues and delay in IRMER sign off. Q4 16/17 update: no eligible patients seen.	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
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.	
17/EM/0075	222172	HRA Approval	Evaluating the tolerance, compliance and acceptability of a nutritionally complete, high energy, high protein, enteral feed in adults – a pilot study		01/02/2017	27/03/2017	27/03/2017							Within 70 days												