Western Sussex Hospitals MHS

Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Duration between VRA and First Patient	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/EM/0118	A multi-centre randomised placebo- controlled trial of prophylactic enteral lactoferrin supplementation to prevent late-onset invasive infection in very preterm infants	22/04/2014													Y	We are a continuing care site for this study and therefore not recruiting patients. The delay between VRA and NHS Permission was the responsibility of the sponsor.	Neither
09/H0715/65	Evaluation the impact of carrier status of obesity-linked genetic variants on the outcome of medical weight loss and bariatric surgery	30/04/2014	24/07/2014	85	No										Y	Study information provided to site was inaccurate. Sponsor's HR department slow to provide relevant documentation regarding CI team research passports.	Sponsor
12/WA/0230	Palliative radiotherapy in addition to self-expanding metal stent for improving outcomes of dysphagia and survival in advanced oesophageal cancer.	03/04/2014	13/02/2015	316	No	Y				Y						Delay caused by need for cross- organisation agreement on IRMER. Organisations providing services were across two regional radiation protection services. Retirement of study research nurse and delay in identifying and recruiting an appropriately trained replacement.	NHS Provider
12/WS/0300 13/SC/0111	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Alirocumab (SAR236553/REGN727) on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome. FOCUS4 - Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	22/04/2014	15/10/2014	176	No			,	Y							Site initiation visit not until 02/07/14. First patient seen 08/08/14. First patient randomised 15/10/14.	Sponsor

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13/NW/0621	The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care (ARCHIE): a double- blind randomised placebo-controlled trial.	12/09/2014									Y					Sponsor requested all sites be research ready in good time for the flu season. Sponsor delay in sending out trial medication - not received until mid February 2015. No potential participants seen between receiving study medication and recruitment window closing at end of March 2015. Next recruitment window opens October 2015.	Sponsor
13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer	04/06/2014											Y	Y		Delay in NHS Permission was due to requirement for Material Transfer Agreement to send samples to a devolved nation. Site only providing five patients in this rare disease area. Retirement of study research nurse and delay in identifying and recruiting an appropriately trained replacement.	Both
13/SW/0132	Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial (MASTER)	04/04/2014	30/06/2014	87	No									Y		Recruitment plan is two patients per year.	Neither
13/LO/1595	COgnitive behavioural therapy vs standardised medical care for adults with Dissociative non-Epileptic Seizures: A multi-centre randomised controlled trial (CODES).	09/09/2014	25/11/2014	77	No							Y					Neither

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13/NS/0143	Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension- Free Mid-Urethral Slings in the Surgical Management Of Female Stress Urinary Incontinence; A Pragmatic Multi-centre Non?Inferiority Randomised Controlled Trial: The SIMS Trial		24/11/2014	60	Yes							Y				Site activation by sponsor 13/10/14.	Neither
12/SW/0206	Accuracy and cost-effectiveness of dynamic contrast enhanced computed tomography in the characterisation of solitary pulmonary nodules	07/07/2014	10/10/2014	95	No						Y					No eligible patients identified during screening until first patient recruited 10/10/14.	Neither
	A Prospective Randomised Phase III Study of Observation Versus Screening MRI And Pre-Emptive Treatment in Castrate Resistant Prostate Cancer Patients With Spinal Metastasis	31/10/2014										Y				Two screen fails. Next eligible patient seen declined to participate on grounds of serious ill health of partner.	NHS Provider
12/WM/0187	A randomised controlled trial of reinforcement of closure of stoma site using a biological mesh	24/10/2014	05/12/2014	42	Yes												
12/NW/0045	A RandoMised study of best Available therapy versus JAK Inhibition in patients with high risk Polycythaemia Vera or Essential Thrombocythaemia who are resistant or intolerant to HydroxyCarbamide	16/09/2014	42032	134	No									Y		Rare disease area.	Neither
	Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture (PROVE)	30/09/2014	42033	121	No					Y						Contract to provide the MSK service was in consultation and staff unable to undertake additional tasks at the time.	NHS Provider

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13/LO/1082	Revascularisation or medical therapy in elderly patients with acute anginal syndromes.	09/12/2014									Y					Participants must be over the age of 80 years and so far have been either too unwell to be eligible or so well that randomisation would be inappropriate.	Neither
08/H1102/112	Safety and efficacy of intensive versus guideline antiplatelet therapy in high risk patients with recent ischaemic stroke or transient ischaemic attack: a randomised controlled trial	03/02/2015								Y						Study not activated at site by sponsor due to NHS Provider staff jury service and annual leave.	NHS Provider
12/EM/0369	Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage TICH2	27/02/2015								Y						Study not activated at site by sponsor due to NHS Provider staff jury service and annual leave.	NHS Provider