13/NW/0621 primary care (ARCHIE): a double-

blind randomised placebo-controlled



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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	SO	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			No						Υ	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. A Randomized, Double-Blind,	03/04/2014			No	Y						Delay caused by need for cross- organisation agreement on IRMER. Organisations providing services were across two regional radiation protection services.	Neither
12/WS/0300	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	22/04/2014			No		Y					Site initiation visit not until 02/07/14. First patient seen 08/08/14. First patient randomised 15/10/14.	Sponsor
13/SC/0111	Coronary Syndrome. FOCUS4? Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme The early use of Antibiotics for at Risk CHildren with InfluEnza in	30/04/2014			No						Y	Lack of clinical equipoise regarding availability of treatment arms, as judged by the Pl. Now resolved.	NHS Provider



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13/YH/0229	GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer	04/06/2014			No								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.	Sponsor
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									Υ		Recruitment plan is two patients per year.	Neither
	COgnitive behavioural therapy vs standardised medical care for adults with Dissociative non-Epileptic Seizures: A multi-centre randomised controlled trial (CODES).	09/09/2014			Currently within 70 days timeframe							Y				No eligible patients seen to date.	Neither
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	25/09/2014			Currently within 70 days timeframe							Υ				Site activation by sponsor 13/10/14.	Neither
12/SW/0206	Accuracy and cost-effectiveness of dynamic contrast enhanced	07/07/2014			No						Υ					No eligible patients identified during screening until first patient recruited 10/10/14.	Neither

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