

Performance in Initiating Research, July 2019

Research Ethics Committee Reference Number	IRAS No	Name of Trial	First Patient Recruited?	Date of First Patient Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and Date First Patient Recruited	Duration between Date Site Selected and Date First Patient Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed by Sponsor	Date Site Confirmed	Non-confirmation Status	Date Site Ready to Start	Reasons for Delay	Comments	Source of Delay
17/EE/0382	220851	PROFILE - Predicting outcomes for Crohn's disease using a molecular biomarker trial	No		32			02/08/18	02/08/18	02/11/17	17/08/18	03/09/18		29/10/18	Sponsor Delays then Staff availability issues	Initial delays due delayed Green Light from sponsor. Subsequent delays due to PI withdrawal from study due to lack of capacity.	Both
17/NW/0460	225455	PEARL - A window of opportunity study to assess the biological effects of progesterone in premenopausal ER-positive, PgR-positive early breast cancer	Yes	16/01/19	8	113	121	17/09/18	17/09/18	20/10/17	18/09/18	25/09/18		20/11/18	Sponsor Delays	Site Initiation Visit held on 20 Sept 2018; Green Light not given until 20 Nov 2018.	Sponsor
18/NE/0092	244145	ELAN - Early versus Late initiation of direct oral Anticoagulants in post-ischaemic stroke patients with atrial fibrillation (ELAN): an international, multicentre, randomised-controlled, two-arm, assessor-blinded trial	Yes	18/01/19	32	53	85	29/08/18	25/10/18	13/08/18	13/11/18	26/11/18		14/01/19	Sponsor Delays	Delayed Green Light date from Sponsor	Sponsor

17/NW/0529	226070	PPAC 2 - The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial	Yes	11/03/19	23	117	140	27/03/18	22/10/18	05/12/17	31/10/18	14/11/18		15/02/19	Sponsor Delays.	Delayed Green Light date from Sponsor	Sponsor
17/SS/0082	222441	SO-START - Start or stop anticoagulants	No		36			25/09/18	26/09/18	05/10/17	18/10/18	01/11/18		21/11/18	Sponsor Delays	Initial delays due to Sponsor. Site Initiation Visit held on 25 Oct 2018; Green Light not given until 21 Nov 2018.	Sponsor
16/NS/0106	212541	RAACENO - Reducing Asthma Attacks in Children using Exhaled Nitric Oxide as a biomarker to inform treatment strategy - a randomised trial	Yes	10/12/18	26	62	88	27/04/18	13/09/18	04/04/17	29/09/18	09/10/18		24/11/18	Contracting Delays	Delays due to Sponsor modifying model agreement; this then caused delayed Site Initiation Visit and then delayed Green Light Date.	Sponsor
18/SS/0033	242190	BICS - A randomised, double-blind placebo controlled trial of the effectiveness of the beta-blocker bisoprolol in preventing exacerbations of COPD	No		45			28/10/18	21/12/18	09/08/18	24/01/19	04/02/19		08/05/19	Sponsor Delays	SIV held on 27 March 2019; Green Light from Sponsor not given until 8 May 2019.	Sponsor
18/EM/0310	239782	C-Stich 2: Emergency Cervical Cerclage to Prevent Miscarriage and Preterm Birth: a Randomised Controlled Trial	No		13			03/01/19	07/03/19	16/11/18	07/03/19	20/03/19			Sponsor Delays	Green Light from Sponsor outstanding	Sponsor
19/WA/0005	24601	ATLANTA - Adjuvant treatment to the local tumour for metastatic prostate cancer: Assessment of novel treatment algorithms	No		21			18/12/18	26/03/19	14/03/19	26/03/19	16/04/19		28/05/19	No patient consented.	Patients sought but no patients consented. (Patients have up-to 6 months from start of Standard of Care treatment before being able to consent to study; patient has been identified).	Neither

16/EM/0322	202096	TWIST - A randomised-controlled trial of thrombolytic treatment with tenecteplase for acute ischaemic stroke upon awakening	No		48			07/02/19	07/02/19	18/08/17	18/03/19	27/03/19		26/04/19	No patient consented.	Patients sought but no patients consented.	Neither
17/WS/0210	231280	ALLEGRO - A placebo controlled randomised trial of intravenous lidocaine in accelerating gastrointestinal recovery after colorectal surgery	Yes	02/07/19	40	71	111	07/01/19	13/03/19	27/04/19	17/04/19	22/04/19		31/05/19	No patient consented.	Patients sought but no patients consented.	Neither
15/LO/0485	138945	SUPPORT - Stitch, Progesterone or Pessary: a Randomised Trial The prevention of pre-term birth in women who develop a short cervix. A multi-centre randomised controlled trial to compare three treatments; cervical cerclage, cervical pessary and vaginal progesterone;	No					13/12/18	01/02/19	15/06/16	18/03/19	16/05/19			Sponsor	SIV not yet held and Green Light not yet given.	Sponsor
19/WA/0019	248285	ROSSINI 2 - Reductions of surgical site infection using several novel interventions	Yes	25/06/19	12	34	46	21/03/19	10/05/19	01/02/19	14/05/19	22/05/19		19/06/19			
19/NW/0158	259931	SCIENCE - Surgery of cast for injuries of the epicondyle in children's elbows	No		22			18/04/19	13/05/19	25/03/19	16/05/19	04/06/19		06/06/19	No patient consented.	Patients sought but no patients consented.	Neither
17/LO/1819	210689	BLADDERPATH - Image Directed Redesign of Bladder Cancer Treatment Pathways	No		24			10/04/19	13/05/19	02/05/19	04/06/19	06/06/19		13/06/19	No patients seen.	No patient identified.	Neither