

Performance in Initiating Research, April 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	Reasons for delay correspond to
17/NS/0018	223787	FUTURE Female Urgency, Trial of Urodynamics as Routine Evaluation; a superiority randomised clinical trial to evaluate the effectiveness and cost effectiveness of invasive urodynamic investigations in management of women with refractory overactive bladder symptoms.	Yes	16/09/18	16	86	102	28/03/18	06/06/18	11/08/17	11/06/18	22/06/18		02/07/18	No patients seen	Participants sought but no eligible participants identified.	NHS Provider
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	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			Sponsor Delays	SIV held on 27 March 2019; Green Light from Sponsor still outstanding.	Sponsor

17/SC/0034	217773	ARK - Antibiotic Reduction and Conservation in Hospitals	No		43			24/01/19	24/01/19	21/03/17	14/02/19	08/03/19			Other	Study is unusual in that the hospital is randomised, not the patients. Study is mainly based upon very large data collection though staff will be consented to provide their opinion once the data collection has started.	Neither
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	07/03/17	16/11/18	07/03/19	20/03/19			Sponsor Delays	Delayed Green Light from Sponsor	Sponsor