Whittington Hospital NHS Trust Performance in Initiating Q3 18/19

HRA Approval Studies

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Participant Recruited?	Date of First Participant Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Participant Recruited	Duration between Date Site Selected and First Participant 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/SC/0139	197936	SPAARK: Study of Peri-Articular Anaesthetic for Replacement of the Knee The clinical and cost effectiveness of periarticular liposomal bupivacaine compared with bupivacaine hydrochloride for post-operative recovery after knee replacement surgery: A multi-centre, blinded, randomised controlled trial. (SPAARK)	Yes	17/05/2018	35	30	65	13/03/2018	13/03/2018	18/09/2017	17/04/2018	17/04/2018	Please Select...	17/04/2018			Please Select...
18/LO/0079	232937	LJPC-401 for iron overload in adults with TDT A Multi-center, Randomized, Open-Label, Parallel-Group Study with LJPC-401 for the Treatment of Myocardial Iron Overload in Adult Patients with Transfusion-Dependent Beta Thalassemia	Yes	04/09/2018	68	84	152	09/02/2018	05/04/2018	23/03/2018	24/04/2018	12/06/2018	Please Select...	12/06/2018	A - Permissions delayed/denied H - Contracting delays	Local sign off was delayed	NHS Provider
16/HRA/5525	210175	MinSHINE 3	Yes	09/07/2018	23	5	28	11/06/2018	11/06/2018	23/01/2017	11/06/2018	04/07/2018	Please Select...				Please Select...
17/LO/0357	202353	Better Conversations with Primary Progressive Aphasia (BCPPA): Communication training to keep families together.	No		59			24/07/2018	17/09/2018	26/04/2017	08/11/2018	15/11/2018	Please Select...	15/11/2018	F - No patients seen	No eligible patients referred.	Neither
17/LO/1596	228894	REACH Pregnancy Circles:An individual-	Yes	22/11/2018	22	51	73	27/07/2018	10/09/2018	03/05/2018	05/10/2018	02/10/2018	Please Select...	29/10/2018	F - No patients seen	Patients sought but no eligible	Neither

		level randomised controlled trial of group antenatal care														patients identified.	
17/NS/0018	223787	Female Urgency, Trial of Urodynamics as Routine Evaluation (FUTURE study); 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.	No					02/08/2018	08/11/2018	11/08/2017			Please Select...		E - Staff availability issues J - Other	The Trust were unable to find a PI for this study and once they did, are awaiting approval of a non-substantial amendment to add PI which has caused delays. In addition, the study team are awaiting new PI to sign the Clinical trial authorisation which is causing further delays.	NHS Provider
18/SW/0039	229163	Induction of labour for predicted macrosomia The 'Big Baby Trial'	No		75			27/07/2018	27/07/2018	20/03/2018	10/10/2018	10/10/2018	Please Select...	30/10/2018	A - Permissions delayed/denied	Lack of engagement between the PI and R&D office	NHS Provider
174/LO/0950	220368	Evaluation of the effect of a post-surgery lifestyle intervention compared to usual care upon post-surgery weight loss and changes in body composition, physical activity levels and health-related quality of life in the first year following bariatric surgery. BARI-LIFESTYLE	Yes	29/05/2018	106	35	141	21/04/2017	08/01/2018	19/07/2018	24/04/2018	24/04/2018	Please Select...	08/11/2018	J - Other	Site changed capacity from PIC to Research site which created delays in recruitment.	Neither
17/LO/0334	214459	FLO-ELA: FLuid Optimisation in Emergency LAparotomy. Open, multi-centre, randomised controlled trial of cardiac output - guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery.	No		81			01/10/2018	01/10/2018	17/08/2017	18/12/2018	21/12/2018	Please Select...		A - Permissions delayed/denied	Permissions not issued in time, therefore unable to commence recruitment in a timely fashion. This was set up under divisional harmonisation.	Sponsor
18/SC/0250	243935	Transforming the mental health treatment of children and young people	No					30/11/2018	03/12/2018	21/05/2018	30/11/2018		Please Select...				Please Select...

		with epilepsy trial (MICE)															
18/LO/2070	246179	A feasibility trial of serial prophylactic exchange blood transfusion (SPEBT) in pregnant women with sickle cell disease (SCD) aiming to improve maternal and infant outcomes TAPS2: Transfusions Antenatally in Pregnant women with SCD	No					06/08/2018	03/12/2018				Please Select...				Please Select...

Whittington Hospital NHS Trust Performance in Delivery Q3 18/19

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial	Comments
17/LO/1147	222154	Tralokinumab monotherapy for moderate-to-severe atopic dermatitis ECZTRA 2 (ECZema TRAlokinumab trial no. 2)	Number Agreed	4	4	Date Agreed	31/05/2018	5	23/03/2018	5	Recruitment Finished	Study closed early as they had reached the recruitment target
17/SC/0244	226900	A randomised, parallel-group, double-blind, double-dummy, active-controlled, multicentre study to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids. ASTEROID 5	Number Agreed	5	5	Date Agreed	03/12/2019	5	25/01/2018	5	Recruitment Finished	Study closed early as they had reached the recruitment target
15/SC/0225	80596	A prospective, observational, multi-centre, cohort study of the G7™ acetabular system used with compatible femoral stems in patients with degenerative disease of the hip	Number Agreed	50	50	Date Agreed	30/06/2018	63	31/01/2018	63	Withdrawn By Host	Study was closed by the site following a change in eligibility criteria initiated by the Sponsor