

Performance in Initiating Clinical Research - Quarter 2 (2018/19)											
All clinical trials selected between 01 October 2018 - 30 September 2019											
Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired West Middlesex University Hospital NHS Foundation Trust on 01 September 2015 and the submission for the former West Middlesex University Hospital NHS Foundation Trust has been subsumed into this submission											
HRA Approval studies											

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Date of recruitment of first participant	Comments	Reasons for delay correspond to:
17/WM/0017	201600	A randomised placebo-controlled trial of mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage	10/04/2017	13/10/2017	18/04/2017	19/10/2017	08/11/2017	29/11/2017	29/11/2017		
16/LO/0831	196728	Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with Community-Acquired Pneumonia (CAP): a randomised controlled trial.	11/10/2017	20/10/2017	11/11/2016	20/11/2017	23/11/2017	04/12/2017	14/12/2017		
17/LO/1169	224716	Efficacy and usability of Ostom-i device in patients with ileostomy. A pilot study.	10/10/2017	30/10/2017	20/10/2017	30/10/2017	31/10/2017	30/11/2017	19/01/2018	Sponsor green light was a month after confirmation of C&C then no eligible patients were seen over the Christmas period. First patient recruited on 19th January 2018.	Sponsor
17/WM/0241	224978	Blood pressure monitoring in high risk pregnancy to improve the detection and monitoring of hypertension	01/09/2017	08/11/2017	09/08/2017	13/11/2017	15/11/2017	28/11/2017	30/11/2017		
15/WM/0036	161768	GAPP 2: A multicentre randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women	05/06/2017	16/11/2017	06/07/2016	21/12/2017	21/12/2017	13/06/2018	13/06/2018	Sponsor had a shortage of IMP for study so sites that confirmed C&C in late 2017 were not given the green light to start recruitment until June 2018.	Sponsor
17/NW/0247	222303	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc in Adult Subjects with Nonalcoholic Steatohepatitis and Liver Fibrosis	20/10/2016	13/12/2017	30/08/2017	21/12/2017	02/02/2018	01/03/2018	19/03/2018	Delays in executing contract with Sponsor (5 weeks from 1st signature to Sponsor signature).	Sponsor
17/LO/1802	199038	Evaluation of the QUIPP App for Triage and Transfer: reducing inappropriate management for threatened preterm labour	12/12/2017	17/01/2018	23/11/2017	17/01/2018	07/02/2018	12/02/2018	12/02/2018		
16/LO/0879	200503	Extend-3: Response guided therapy with sofosbuvir and velpatasvir for 12 or 24 weeks in patients with genotype 3 chronic hepatitis C virus: is longer therapy worthwhile?	22/11/2017	01/02/2018	20/12/2017	09/02/2018	21/02/2018	04/06/2018	N/A	Site green lighted by Sponsor four months after confirmation of C&C due to technical/IT issues. Sponsor then closed sites to recruitment on the 1st October 2018 before we had recruited.	Sponsor
17/LO/1245	208149	Metronidazole Versus lactic acid for Treating bacterial vAginosis?VITA	27/11/2017	11/01/2018	12/09/2017	08/01/2018	23/01/2018	23/02/2018	01/03/2018	Sponsor issued green light 1 month after confirmation of capacity and capability. Site recruited first patient 1 week after receiving the green light.	Sponsor
17/SC/0244	226900	ASTEROID 5 (version 1.0): 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.	30/01/2017	11/01/2018	27/07/2017	05/12/2017	18/01/2018	19/01/2018	28/06/2018	Sponsor temporarily suspended recruitment due to safety concerns in Feb 2018. Recruitment has now restarted and our first patient was recruited in June.	Both
17/SW/0279	231649	MO39171 - Atezolizumab in locally advanced or metastatic NSCLC	29/06/2017	12/02/2018	01/02/2018	23/02/2018	23/02/2018	23/02/2018	20/03/2018		
17/LO/2041	234256	Chronic Hypertension in pregnancy IMPLEMENTATION study (CHAMPION)	01/02/2018	08/02/2018	11/01/2018	23/01/2018	19/02/2018	22/02/2018	08/03/2018		
17/WA/0173	229298	An exploratory study to investigate the benefits and costs of ReCell with meshed autografts versus autografts alone in burns	11/10/2017	17/05/2018	03/10/2017	16/05/2018	26/06/2018		N/A	Sponsor abandoned study on 21st September after funding was pulled.	Sponsor
18/LO/0559	236730	Feasibility Randomized-Controlled Trial of Online Acceptance and Commitment Therapy for Painful Peripheral Neuropathy in People Living with HIV: The OPEN Feasibility Study	06/06/2018	06/06/2018	26/04/2018	06/06/2018	09/07/2018	18/07/2018	01/08/2018		
18/SC/0024	219560	Nail bed INJury Analysis (NINJA): Should the nail plate be replaced or discarded after nail bed repair in children?	30/04/2018	08/05/2018	20/02/2018	13/06/2018	14/06/2018	13/07/2018	16/07/2018		
18/LO/0900	154432	Withholding Enteral feeds Around packed red cell Transfusion to prevent necrotising enterocolitis in preterm neonates: a multi-centre, electronic patient record (EPR), randomised controlled point-of-care pilot trial (WHEAT)	10/05/2018		09/07/2018	06/07/2018	09/07/2018	08/08/2018	12/10/2018		
17/WH/0120	208838	A pragmatic multi-centre randomised controlled non inferiority, cost effectiveness trial comparing injections of collagenase into the cord to surgical correction in the treatment of moderate Dupuytren's Contracture in adult patients (DISC)	12/06/2018	18/07/2018	25/05/2017	07/08/2018	15/08/2018	25/09/2018	N/A		
17/NW/0529	226070	The impact of postoperative Packing of Perianal Abscess Cavities: a multicentre randomised controlled trial (PPAC 2)	23/07/2018	23/07/2018	05/12/2017	31/08/2018	31/08/2018	20/09/2018	21/09/2018		
18/LO/0773	245000	LUSTRUM cross-over cluster randomised controlled trial of Accelerated Partner Therapy (APT) to improve partner notification outcomes for heterosexual people with sexually transmitted Chlamydia trachomatis infection	27/07/2018	30/08/2018	23/07/2018	05/09/2018	12/09/2018	12/09/2018	N/A	Data entry part of study has started - recruitment into the clinical trial part of the study has not yet begun	
17/NE/0301	212683	IN-UK-311-3956: A Study of the Switch of Tenofovir disoproxil fumarate to Tenofovir alafenamide fumarate and the Effect on Glomerular Function in Chronic Hepatitis B and HIV co-infected individuals.	04/07/2018	31/08/2018	04/12/2017	01/10/2018	09/10/2018		N/A	Study not yet green lighted so recruitment has not yet begun.	
18/LO/1150	239096	Audio-recording of consent for anaesthesia for elective caesarean section ? a pilot study	16/05/2018	06/09/2018	17/08/2018	17/09/2018	17/09/2018	17/09/2018	01/10/2018		
18/WA/0161	238902	An open-label, multi-centre, randomised, switch study to evaluate the virological efficacy over 96 weeks of 2-drug therapy with DTG+RPV FDC in antiretroviral treatment-experienced HIV-1 infected subjects virologically suppressed with NNRTIs resistance mutation K103N (WISARD)	10/09/2018	28/09/2018	04/10/2018				N/A	Site not yet confirmed	