

## Performance in Initiating Clinical Research - Quarter 1 (2019/20)

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

All clinical trials hosted between 1st July 2018 and 30th June 2019

HRA Approval studies

Id	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 First Participant Recruited	Comments	Reasons for Delay correspond to
143404	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			Sponsor has not initiated or green lighted site yet.	Sponsor
143405	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		Please Select...
143406	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	08/11/2018	04/10/2018	07/12/2018	18/12/2018	19/12/2018	12/03/2019	Site had a pool of potentially eligible patients whose medication was changed during set up resulting in them no longer being eligible.	NHS Provider
143407	18/SW/0039	229163	The 'Big Baby Trial'	24/09/2018	23/11/2018	05/12/2018	28/11/2018	05/12/2018	07/12/2018			Please Select...
143408	18/LO/2068	254238	A multicenter, open-label, sponsor-blinded, randomized, active-controlled, parallel group, pivotal study to evaluate the efficacy, safety, and tolerability of murepavadin given with ertapenem versus an anti-pseudomonal ?-lactam-based antibiotic in adult subjects with nosocomial pneumonia suspected or confirmed to be due to Pseudomonas aeruginosa.	19/09/2018	12/11/2018						REC unfavourable opinion. Sponsor resubmitting to REC and HRA. No HRA Approval in place yet.	Sponsor
143409	17/LO/2093	228763	A phase IV, open-label pilot study investigating non-invasive markers of hepatic fibrosis in people living with HIV-1 and non-alcoholic fatty liver disease randomised to receiving optimised background therapy (OBT) plus maraviroc or OBT	11/06/2018	14/02/2019	26/02/2018	18/02/2019	19/02/2019	20/02/2019			Please Select...
143410	16/WS/0057	193580	A randomised, open-label trial of a Multimodal Intervention (Exercise, Nutrition and Anti-inflammatory Medication) plus standard care versus standard care alone to prevent / attenuate cachexia in advanced cancer patients undergoing chemotherapy.	14/11/2018	07/02/2019	04/08/2016	12/04/2019	18/03/2019	12/04/2019			Please Select...
143411	18/SC/0454	249509	Perioperative Ischemic Evaluation-3 Trial	05/02/2019	05/02/2019	16/01/2019	18/03/2019	22/03/2019			SIV not happened yet. Site not yet green lighted by Sponsor.	Sponsor

143412	18/WM/0352	241385	An Open-Label, Multi-Centre, Randomised Study to Investigate Integrase Inhibitor Versus Boosted Protease Inhibitor Antiretroviral Therapy for Patients with Advanced HIV Disease. The Late Presenter Treatment Optimisation Study (LAPTOP).	21/01/2019	21/03/2019	15/01/2019							Please Select...	
143413	18/YH/0017	231431	Improving the safety and continuity of medicines management at care transitions	23/08/2018	11/01/2019	01/03/2018	11/01/2019	19/02/2019	03/04/2019				Please Select...	
145881		227239	A single centre randomised controlled trial investigating the efficacy of The Zoo, a form of digital distraction as an analgesic and anxiolytic in the paediatric emergency department										Please Select...	
	18/LO/1537			23/04/2018	18/01/2019	18/01/2019	08/05/2019	08/05/2019	09/05/2019					
145882		252294	When to Induce Labour to Limit risk in pregnancy hypertension ? a multicentre, randomised controlled trial										Please Select...	
	18/LO/2033			13/02/2019	04/04/2019	10/01/2019	07/05/2019	07/05/2019	06/06/2019					
145883		243519	A Phase 3 Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Upadacitinib in Adolescent and Adult Subjects with Moderate to Severe Atopic Dermatitis								05/06/2019		Please Select...	
	18/LO/1352			07/09/2018	09/04/2019	03/01/2019	17/04/2019	17/04/2019	23/04/2019					
145884		187932	Nucleos(t)ide withdrawal in HBeAg negative hepatitis B virus infection to promote HBsAg clearance. (NUC-B)										Please Select...	
	16/LO/1318			25/10/2018	12/04/2019	21/09/2016	07/05/2019	08/05/2019	14/05/2019					
145885		259342	A Randomized, Double-Blind, Placebo-Controlled Study of Diazoxide Choline Controlled-Release Tablet (DCCR) in Patients with Prader-Willi Syndrome									10/07/2019	Please Select...	
	19/SC/0122			25/10/2018	08/05/2019	07/05/2019	23/05/2019	23/05/2019	04/06/2019					
145886		250289	Molecular Diagnostics for Hospital-Acquired and Ventilator-Associated Pneumonia on Antimicrobial Stewardship and Patient Outcomes in UK Critical Care: A Multicentre Randomised Controlled Trial.										Please Select...	
	19/LO/0400			01/04/2019	02/06/2019	09/04/2019	01/07/2019	02/07/2019	04/07/2019					
145887		191390	STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre Randomized Controlled Trial										Please Select...	
	17/LO/0621			16/11/2018	03/06/2019	22/05/2017	18/06/2019	19/06/2019	05/07/2019					
145888		261913	Pharmacokinetics of plasma doravirine once daily over 72 hours following drug intake cessation in healthy volunteers									25/06/2019	Please Select...	
	19/LO/0666			01/01/2019	10/06/2019	10/06/2019	10/06/2019	10/06/2019	12/06/2019					
145889			A randomised, open-label trial of a Multimodal Intervention (Exercise, Nutrition and Anti-inflammatory Medication) plus standard care versus standard care alone to prevent / attenuate cachexia in advanced cancer patients undergoing chemotherapy.										Please Select...	
	16/WS/0057	193580		14/11/2018	07/02/2019	08/08/2016	26/03/2019	18/03/2019	12/04/2019					
145890			An Open-Label, Multi-Centre, Randomised Study to Investigate Integrase Inhibitor Versus Boosted Protease Inhibitor Antiretroviral Therapy for Patients with Advanced HIV Disease. The Late Presenter Treatment Optimisation Study (LAPTOP).									21/06/2019	Site target just 2 patients - study very difficult to recruit to.	Both
	18/WM/0352	241385		21/01/2019	21/03/2019	15/01/2019	08/04/2019	18/04/2019	09/05/2019					