

Performance in Initiating Clinical Research - Quarter 1 (2018/19)

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 01 April 2018 - 31 March 2019

HRA Approval studies

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Patient Recruited?	Benchmark Met	Date Study Initiated	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Reasons for Delay	Comments	Reasons for delay correspond to:
16/SS/0014	187949	Gem3- A double blind placebo controlled trial of a combination of methotrexate and gefitinib versus methotrexate alone as a treatment for ectopic pregnancy	Yes	No		25/05/2017	25/07/2017	14/10/2016	07/08/2017	09/08/2017	13/09/2017		No eligible patients seen between Sponsor Green Light and the end of December 2017. First patient recruited in early January.	NHS Provider
17/YH/0013	213247	A RandomizEd trial of ENTERal Glutamine to minimIZE thermal injury	Yes	No		20/04/2017	05/09/2017	30/05/2017	05/09/2017	20/09/2017	21/09/2017		No patients matching the inclusion/exclusion criteria presented in the Burns ICU unit during the 30 day period	NHS Provider
17/LO/0887	226610	Icarewean- Weaning from mechanical ventilation: comparison of open-loop decision support system and routine care, in general medical ICU.	Yes	Yes		11/09/2017	11/09/2017	11/09/2017	26/09/2017	26/09/2017	26/09/2017			Please Select...
17/WM/0017	201600	A randomised placebo-controlled trial of mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage	Yes	Yes		10/04/2017	13/10/2017	18/04/2017	19/10/2017	08/11/2017	29/11/2017			Please Select...
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.	Yes	Yes		11/10/2017	20/10/2017	11/11/2016	20/11/2017	23/11/2017	04/12/2017			Please Select...
17/LO/1169	224716	Efficacy and usability of Ostom-i device in patients with ileostomy. A pilot study.	Yes	No		10/10/2017	30/10/2017	20/10/2017	30/10/2017	31/10/2017	30/11/2017		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	Yes	Yes		01/09/2017	08/11/2017	09/08/2017	13/11/2017	15/11/2017	28/11/2017			Please Select...

15/WM/0036	161768	GaPP2:A multicentre randomised controlled trial of the efficacy and mechanism of action of gabapentin for the management of chronic pelvic pain in women	No	No		05/06/2017	16/11/2017	06/07/2016	21/12/2017	21/12/2017	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	Yes	No		20/10/2016	13/12/2017	30/08/2017	21/12/2017	02/02/2018	01/03/2018		Delays in executing contract with Sponsor (5 weeks from 1st signature to Sponsor signature).	Sponsor
17/LO/1245	208149	Metronidazole Versus lactic acid for Treating bacterial vAginosis?VITA	Yes	Yes		27/11/2017	11/01/2018	12/09/2017	08/01/2018	23/01/2018	23/02/2018		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.	Yes	No		30/01/2017	11/01/2018	27/07/2017	05/12/2017	18/01/2018	19/01/2018		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/LO/1802	199038	Evaluation of the QUIPP App for Triage and Transfer: reducing inappropriate management for threatened preterm labour	Yes	Yes		12/12/2017	17/01/2018	23/11/2017	17/01/2018	07/02/2018	12/02/2018			Please Select...
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?	No	Within 70 Days		22/11/2017	01/02/2018	20/12/2017	09/02/2018	21/02/2018	04/06/2018		Site green lighted by Sponsor four months after confirmation of C&C due to technical/IT issues.	Sponsor
17/LO/2041	234256	Chronic Hypertension in pregnancy iMplementation study (CHAMPION)	Yes	Yes		01/02/2018	08/02/2018	11/01/2018	23/01/2018	19/02/2018	22/02/2018			Please Select...
17/SW/0279	231649	MO39171 - Atezolizumab in locally advanced or metastatic NSCLC	Yes	Yes		29/06/2017	12/02/2018	01/02/2018	23/02/2018	23/02/2018	23/02/2018			Please Select...
18/SC/0024	219560	Nail bed INJury Analysis (NINJA): Should the nail plate be replaced or discarded after nail bed repair in children?	No	Please Select...		30/04/2018	08/05/2018	20/02/2018	13/06/2018	14/06/2018	13/07/2018			Please Select...
17/WA/0173	229298	An exploratory study to investigate the benefits and costs of ReCell with meshed autografts versus autografts alone in burns	No	Please Select...		11/10/2017	17/05/2018	03/10/2017	16/05/2018	26/06/2018			SIV scheduled for 26/7/2018. Site not yet open to recruitment.	Please Select...

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	No	Please Select...		06/06/2018	06/06/2018	26/04/2018	06/06/2018	09/07/2018	18/07/2018				Please Select...
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