

Performance in Initiating Clinical Research - Quarter 4 (2017/18)

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 2017 - 31 March 2018

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:
17/YH/0006	148493	HIP fracture Accelerated surgical Treatment And Care track (HIP ATTACK) Trial	Yes	No		08/11/2016	12/04/2017	08/02/2017	01/06/2017	19/06/2017	19/06/2017	Contracting delays	Sponsor is based in Canada. Sponsor took a long time to sign and return contracts to site.	Sponsor
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			
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 patients consented	No eligible patients seen between Sponsor Green Light and the end of December 2017. First patient recruited in early January.	NHS Provider
16/NE/0415	217915	A Phase 2a, Open-Label Study to Evaluate the Safety, Pharmacokinetics and Efficacy of the Combination of AL-335 and Odalasvir, with or without Simeprevir, in Treatment-Na?ve Subjects with Genotype 1, 2 or 3 Chronic Hepatitis C infection with or without compensated Child Pugh A Cirrhosis	No	No		23/03/2017	16/05/2017	28/02/2017	21/08/2017	21/08/2017	21/08/2017	Closed by sponsor	Sponsor discontinued the development of IMP with immediate effect and stopped recruitment on the 31st August 2017 - just 10 days after the Trust confirmed capacity and capability. No patients were recruited in this window.	Sponsor
17/LO/0089	219229	A Phase 2, Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Sofosbuvir/Velpatasvir for 12 Weeks in Subjects with Chronic HCV Infection Who are on Dialysis for End Stage Renal Disease	Yes	No		03/11/2016	26/05/2017	27/03/2017	05/06/2017	16/06/2017	20/06/2017	Rare diseases	Trust target is 1 patient only. 2 patients screened to date. One failed screening. The second patient was seen in early February 2018 and was recruited.	NHS Provider

16/LO/0251	196628	Fetal Atrial Flutter & Supraventricular Tachycardia (FAST) Therapy Trial	No	No		30/09/2016	31/05/2017	09/08/2016	15/06/2017	15/06/2017	08/03/2018	Sponsor delays	Confirmation of C&C was in June 2017. The SIV took place 08/01/2018 and the site was green lighted in March 2018.	Sponsor
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 seen	No patients matching the inclusion/exclusion criteria presented in the Burns ICU unit during the 30 day period	NHS Provider
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			
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			
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 delays, no patients seen	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			
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		Sponsor delays	Sponsor has a shortage of IMP for study so recent sites have not yet received any IMP and therefore have not been given green light to start recruitment. Site not open to recruitment yet.	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	No	No		20/10/2016	13/12/2017	30/08/2017	21/12/2017	02/02/2018	01/03/2018	Sponsor delays, contracting delays	Delays in executing contract with Sponsor (5 weeks from 1st signature to Sponsor signature). Also 1st patient has been consented but the screening window for this study is 45 days long so enrollment is unconfirmed at time of the Q4 17-18 PII report.	Sponsor
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			
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		Sponsor delays	Site not green lighted yet by 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 delays	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.	No	No		30/01/2017	11/01/2018	27/07/2017	05/12/2017	18/01/2018	19/01/2018	Suspended by sponsor, no patients consented	Sponsor temporarily suspended recruitment due to safety concerns in Feb 2018. Recruitment has restarted but no patients have agreed to take part yet.	Both
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			
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			