

Performance in Initiating Clinical Research - Quarter 3 (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 West Middlesex University Hospital NHS Trust has been subsumed into this submission

All clinical trials hosted between 01 October 2017 - 31 December 2017

HRA Approval Studies

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	First Patient Recruited?	Benchmark Met	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:
16/LO/0673	195021	Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial (Sante project)	Yes	Yes	07/12/2016	26/01/2017	10/08/2017	01/02/2017	01/02/2017	N/A	02/02/2017			
16/LO/206	209688	Optimisation of Peri-operative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial: Open, multi-centre, randomised controlled trial of cardiac output-guided fluid therapy with low dose inotrope infusion compared to usual care in patients undergoing major elective gastrointestinal surgery.	No	No	05/01/2017	28/03/2017	06/01/2017	03/05/2017	03/05/2017	N/A	13/08/2017	D - Sponsor Delays	IMP supply issues meant site was not green lighted until 3 months after confirmation of capacity and capability. No eligible patients have been seen at Chelsea and Westminster Hospital and study is currently suspended at site. Trust is currently looking to open the study at West Middlesex Hospital in 2018.	Sponsor
17/LO/0012	213544	Clinical safety & efficacy of a new infant formula with specific medical purpose (FSMP) containing 2 human milk oligosaccharides (HMOs)	No	No	01/11/2016	05/01/2017	13/03/2017	27/04/2017	05/05/2017	N/A	04/08/2017	D - Sponsor delays, F - No patients seen	Study proved very hard to recruit to. Trust now exploring local PIC sites with Sponsor.	Sponsor
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	N/A	19/06/2017	H - 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	N/A	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	N/A	13/09/2017	G - 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-Naïve 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	N/A	21/08/2017	C - 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	No	No	03/11/2016	26/05/2017	27/03/2017	05/06/2017	16/06/2017	N/A	20/06/2017	I - Rare diseases	Trust target is 1 patient only. 2 patients screened to date. One failed screening. The second is due in for baseline assessments early February 2018.	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		N/A - site not green lighted yet	D - Sponsor Delays	SIV took place 08/01/2018. Site yet to receive green light from Sponsor. Site not open to recruitment yet.	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	F - 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	N/A	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	N/A	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	N/A	30/11/2017	D - Sponsor Delays, F - 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	N/A	28/11/2017			
15/WM/0036	161768	GaPP???:?A?multicentre?randomised?controlled?trial?of?t he?efficacy?and?mechanism?of?action?of?gabapentin?for ?the?management?of?chronic?pelvic?pain?in?women	No	Within 70 Days	05/06/2017	16/11/2017	06/07/2016	21/12/2017	21/12/2017	N/A	N/A - site not green lighted yet	D - 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	Within 70 Days	20/10/2016	13/12/2017	30/08/2017	N/A	N/A	N/A	N/A - site not green lighted yet		Date site confirmed and confirmed by Sponsor outside or Q3 PI reporting period.	