

Performance in Initiating Clinical Research - Quarter 2 (2017/18)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired West Middlesex University Hospital NHS Trust on 01 September 2015, and the submission for the former West Middlesex University Hospital NHS Trust has been subsumed into this submission

All clinical trials Hosted between 01 October 2016 – 30 September 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/1205	193598	Psychoeducational intervention for women prescribed tamoxifen	No	No	24/06/2016	20/10/2016	13/10/2016	16/11/2016	15/11/2016	N/A	16/11/2016	E - Staff availability issues	The research nurse supporting the study was off sick for a long period of time. The Sponsor closed this study in March 2017 having recruited sufficient participants from other sites.	NHS Provider
16/SC/0216	143117	The OPTIMIST-A Trial	Yes	No	30/10/2016	30/10/2016	20/09/2016	15/02/2017	22/02/2017	N/A	23/02/2017	D - Sponsor Delays	Confirmation of C&C at site was delayed due to protracted contract negotiations with non-UK Sponsor (Australian) - non-model agreement, non GDP payments plus a substantial amendment by Sponsor all severley delayed set up.	Sponsor
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/189	213918	A Phase 2, Double-Blind, Randomized Study Evaluating the Safety, Tolerability, and Efficacy of GS-4997 in Combination with Prednisolone versus Prednisolone Alone in Subjects with Severe Alcoholic Hepatitis (AH)	Yes	No	03/07/2017	09/11/2016	09/01/2017	23/03/2017	07/04/2017	N/A	07/04/2017	F - No patients seen	Tight eligibility criteria and patients unwilling to consent.	NHS Provider
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	No	No	05/01/2017	28/03/2017	06/01/2017	03/05/2017	03/05/2017	N/A		D - Sponsor Delays	SIV has not happened yet. Site has not had Sponsor green light yet.	Sponsor

		elective gastrointestinal surgery.												
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		D - Sponsor Delays	SIV has not happened yet (due late July 2017). Site has not received Sponsor green light	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	No	Within 70 Days	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 yet.	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