

Performance in Initiating Clinical Research - Quarter 1 (2017/17)

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 July 2016 – 31 June 2017

Research Ethics Committee Reference Number	Submission Type	Name of Trial	First Patient Recruited?	Date of First Patient Recruited	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Comments
16/EE/0223	HRA Approval	DIAB5124	No		10/02/2016	06/09/2016	19/08/2016	21/09/2016	21/09/2016	21/09/2016	Study hard to recruit to nationally. The changing therapy landscape in type 2 diabetes with all the new treatments have pushed insulins further down the pathway Hence the paucity of suitable numbers?. Sponsor has closed study to recruitment. No patients

											recruited at site.
16/LO/1205	HRA Approval	Psychoeducational intervention for women prescribed tamoxifen	No		24/06/2016	20/10/2016	13/10/2016	16/11/2016	15/11/2016	16/11/2016	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.
16/SC/0216	HRA Approval	The OPTIMIST-A Trial	Yes	25/03/2017	30/10/2016	30/10/2016	20/09/2016	15/02/2017	22/02/2017	23/02/2017	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 severely delayed set up.
16/LO/0673	HRA Approval	Sexual risk reduction interventions for patients attending sexual health clinics; feasibility to conduct an effectiveness trial (Sante project)	Yes	10/03/2017	07/12/2016	26/01/2017	10/08/2017	01/02/2017	01/02/2017	02/02/2017	

16/LO/1282	HRA Approval	QualIVL	Yes	06/03/2017	23/08/2016	23/08/2016	23/08/2016	02/03/2017	02/03/2017	02/03/2017	Sponsor made an amendment to the study following confirmation of capacity and capability which delayed the start of recruitment
16/LO/189	HRA Approval	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	03/07/2017	03/07/2017	09/11/2016	09/01/2017	23/03/2017	07/04/2017	07/04/2017	Tight eligibility criteria and patients unwilling to consent.

16/LO/206	HRA Approval	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		05/01/2017	28/03/2017	06/01/2017	03/05/2017	03/05/2017		SIV has not happened yet. Site has not had Sponsor green light yet.
17/LO/0012	HRA Approval	Clinical safety & efficacy of a new infant formula with specific medical purpose (FSMP) containing 2 human milk oligosaccharides (HMOs)	No		01/11/2016	05/01/2017	13/03/2017	27/04/2017	05/05/2017		SIV has not happened yet (due late July 2017). Site has not received Sponsor green light

17/YH/0006	HRA Approval	HIP fracture Accelerated surgical Treatment And Care track (HIP ATTACK) Trial	Yes	03/07/2017	08/11/2016	12/04/2017	08/02/2017	01/06/2017	19/06/2017	19/06/2017	Sponsor is based in Canada. Sponsor took a long time to sign and return contracts to site.
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