

Performance in Delivering Clinical Research - Quarter 2 (2018/19)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired West Middlesex University Hospital NHS Foundation Trust on 01/09/2015, and the submission for the former West Middlesex University Hospital NHS Trust has been subsumed into this submission

All hosted, commercial clinical trials closed to recruitment between 01 October 2018 - 30 September 2019

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Target Number Of Patients Agreed?	Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	Target Date To Recruit Patients Agreed?	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Total Number Of Study Participants Recruited	Date That The Trial Closed To Recruitment	Reason For Closure Of Trial	Comments
16/LO/1891	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)	Range Agreed	1	3	Date Agreed	01/08/2017	1	1	31/12/2017	Recruitment Finished	
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	Range Agreed	1	3	Date Agreed	28/08/2017	0	1	07/02/2018	Recruitment Finished	Study recruitment window was extended beyond the original anticipated end date. This allowed us to recruit one patient before recruitment ended.
14/SC/1161	155743	Prospective, single-arm, multi-centre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients.	Number Agreed	2	2	Not Available / Not Agreed			2	03/05/2018	Recruitment Finished	
17/LO/0012	213544	Clinical safety & efficacy of a new infant formula with specific medical purpose (FSMP) containing 2 human milk oligosaccharides (HMOs)	Range Agreed	1	5	Date Agreed	28/02/2018	0	0	09/05/2018	Recruitment Finished	No eligible patients identified at site.
15/NE/0167	171524	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation - MILLENIUM	Range Agreed	1	2	Not Available / Not Agreed			0	21/09/2018	Withdrawn By Sponsor	One patient consented at site but screening kit expired during screening window and patient did not get enrolled. No other eligible patients were identified before Sponsor closed out site.
17/EM/0157	222140	An International Phase 3 Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study to Evaluate Relugolix Co-Administered with and without Low-Dose Estradiol and Norethindrone Acetate in Women with Heavy Menstrual Bleeding Associated with Uteri	Number Agreed	3	3	Not Available / Not Agreed			0	24/09/2018	Withdrawn By Sponsor	Sponsor closed study across whole UK as no patients in UK passed screening.