

Performance in Delivering Clinical Research - Quarter 1 (2018/19)

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 Trust has been subsumed into this submission

All hosted, commercial clinical trials closed to recruitment between 01 April 2018 - 31 March 2019

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Minimum Number Of Patients Agreed	Maximum Number Of Patients Agreed	Target Date to Recruit Patients Agreed	Date Agreed to recruit target number of patients	Total Number Of Patients Recruited At The Agreed Target Date	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure of Trial	Comments
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Hepatitis C infection with or without compensated Child Pugh A Cirrhosis		5	5	Not Available / Not Agreed		31/08/2017	0	Withdrawn By Sponsor	Sponsor discontinued the development of IMP with immediate effect and stopped recruitment on the 31st August 2017 - just 10 days after the Trust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.
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)		1	3	Date Agreed	01/08/2017	31/12/2017	1	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		1	3	Date Agreed	28/08/2017	07/02/2018	0	1 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.		2	2	Not Available / Not Agreed		03/05/2018	2	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)		1	5	Date Agreed	28/02/2018	09/05/2018	0	Recruitment Finished	No eligible patients identified at site.