

Performance information on the initiation and delivery of clinical research

The Department of Health requires, via the new National Institute for Health Research (NIHR) contracts with providers of NHS services, the publication on a quarterly basis of information regarding: the 70-day benchmark for clinical trial initiation; and the recruitment to time and target for commercial contract clinical trials.

Clinical Trials for which NHS Permission was given – End of Quarter 4, covering April 2014 to March 2015.

Performance in Initiating all Clinical Trials:

REC Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	Date of First Patient Recruited	70-day Benchmark	Comments
12/LO/1514	Lamotrigine And Borderline Personality Disorder: Investigating Long-Term Effectiveness (LABILE)	15/04/2014	17/04/2014	15/05/2014	30	Benchmark Met
13/EE/0063	Minocycline in Alzheimer's Disease Efficacy (MADE) trial	28/04/2014	06/05/2014	23/05/2014	25	Benchmark Met
12/NW/0441	A Trial of LMTM in Patients with behavioural variant Fronto-Temporal Dementia (TRx-237-007)	12/09/2014	18/09/2014			Site opened in last 3 months of trial. 28 patients pre-screened and 2 patients consented but not randomised within the 70-day period. Closed early by sponsor on 12/12/2014 as global recruitment target achieved.

REC Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	Date of First Patient Recruited	70-day Benchmark	Comments
12/LO/1537	The E Sibling Project – exploratory randomised controlled trial of an online multi-component psychoeducational intervention for siblings of individuals with first episode psychosis	30/09/2014	08/10/2014	13/03/2015	164	Site opened in last 3 months of trial with recruitment due to end 31/12/2014. Trial then extended to 31/03/2015. All potential participants expressing interest within the 70-day period have not met eligibility criteria being younger than 16 years, and one did not have access to internet.
14/EM/1084	Depression and Self-harm Study (e-DASH) V1.1	08/01/2015	16/01/2015	13/02/2015	36	Benchmark Met

Performance in Delivering Commercial Contract Clinical Trials

REC Reference Number	Name of Trial	Target number of patients	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
12/NW/0441	A Trial of LMTM in Patients with behavioural variant Fronto-Temporal Dementia (TRx-237-007)	1	31/12/2014	Closed - In Follow Up	No	Site opened in last 3 months of trial. 28 patients pre-screened and 2 patients consented but not randomised. A 3rd potential participant identified but notification received from sponsor on 12/12/14 that global recruitment numbers achieved and no further participants could be enrolled.