

Performance in Initiating Clinical Research Q3 2014 - 15
70-day benchmark, valid application to first participant recruited

Research Ethics Committee Number	Name of Trial	Date of Receipt of Valid Research Application	Date of First Patient Recruited	Benchmark Met	Comments
13/SC/0046	Feasibility study for a community based intervention for individuals with severe CFS/ME	05/07/2013	12/03/2014	No	The Sponsor did not have staff available to carry out the study at this site, therefore local governance was suspended until we were in receipt of valid research passports and could put appropriate HR arrangements in place for research staff.
13/EE/0063	Minocycline in Alzheimer's Disease efficacy trial: The MADE Trial	13/03/2014	26/06/2014	No	Site was urged by sponsor to submit the SSI on 12 March despite localised documents not being in place; NHS permission was provided 23 March. The sponsor then delayed giving the site 'Green Light' as they required an amendment to be approved first. The site was also awaiting approved, localised documents from the sponsor in May despite site agreement being fully executed on 19/05. Green light was finally given by the sponsor 2nd June.
13/SC/0386	Long-term safety and efficacy of ABT-126 in subjects with schizophrenia: a double-blind extension study for subjects completing study M10-855	22/01/2014	07/04/2014	No	1 participant was eligible to continue to the extension study from the main study; a second potentially eligible participant withdrew their consent prior to the extension study. A delay in recruiting the eligible participant was due to a medical condition that needed further investigation and treatment before the participant could be recruited. At that point the participant then cancelled the scheduled visit due to sickness and diarrhoea which further delayed the recruitment visit.
13/NW/0727	A randomised, double-blind, placebo-controlled, single-dose, study of the effects of SEP 363856 and Amisulpride on bold-FMRI signal in healthy male and female volunteers with high or low schizotype characteristics	07/03/2014	27/03/2014	Yes	
14/SC/0107	Cognitive Therapy for Fears about Other People CBT+	16/04/2014	25/06/2014	Yes	
12/WA/0338	Reducing pathology in Alzheimer's Disease through Angiotensin Targeting. the RADAR Trial. A phase II, randomised, double blind, placebo-controlled trial to evaluate the effect of Losartan on brain tissue in patients diagnosed with Alzheimer's Disease	01/07/2014	10/11/2014	No	NHS permission given on 7th July 2014 but Green Light' was delayed by Sponsor until 1st October 2014 due to delays in obtaining MRI scan validation and provision of unblinding service by Sponsor Pharmacy. The CI of the study has confirmed that the delay is due to the Sponsor.
13/LO/1758	A phase III, randomised, placebo controlled, parallel group, double blind, clinical trial to study the efficacy and safety of MK8931 (SCH 900931) in subjects with amnesic mild cognitive impairment due to Alzheimer's Disease (Prodromal AD)	08/07/2014	28/07/2014	Yes	
13/LO/0699	Evaluating the effects of the novel GLP-1 analogue, liraglutide, in patients with Alzheimer's disease (ELAD study)	22/10/2014	14/01/2015	No	Delays due to sponsor taking 19 days to return fully executed agreement to the Trust and staff resourcing issues due to illness.
13/YH/0016	Evaluating the effectiveness and cost effectiveness of Dementia Care Mapping (DCM) to enable person-centred care for people with dementia and their carers: A cluster randomised controlled trial in care homes (DCM EPIC trial)	26/10/2014	24/11/2014	Yes	2 Care homes have been recruited, which is in line with the agreed study target.