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.

Report period: covering April 2016 to March 2017- End of Quarter 4

1. Performance in initiating all Clinical Trials:

(For every clinical trial (regardless of funder or inclusion in NIHR CRN Portfolio) for which it gave NHS permission in the previous twelve months.)

*National guidance updated for Q3 16-17 to exclude any Pre-Health Research Authority (HRA) approved clinical trials. Only one study was therefore eligible for submission in Q3 although all clinical trials previously submitted are included here on the website. In Q4 there was one clinical trial initiated but was ineligible for submission as Pre-HRA approved although this is included here on the website.

HRA status*	HRA (Submitted) Q3	PRE HRA (excluded) Q3	PRE HRA (excluded) Q3	PRE HRA (excluded) Q3	PRE HRA (excluded) Q3	PRE HRA (excluded) Q3	PRE HRA (excluded) Q4
Id	95356	95354	95355	95357	95358	95359	Not Applicable
Research Ethics Committee Reference Number	16/SS/0038	15/SC/0432	15/SC/0434	13/EM/0161	13/LO/0314	13/LO/0621	15/YH/0531
Integrated Research Application System Number	198888	181387	181955	195907	126215	129996	166392
Submission Type	HRA Approval	HRA Approval	HRA Approval	HRA Approval	HRA Approval	HRA Approval	HRA Approval

Name of Trial	A 52-Week, Open-Label, Prospective, Multicenter, International Study of a Transition to the Paliperidone Palmitate 3-Month Formulation In Patients with Schizophrenia Previously Stabilized on the Paliperidone Palmitate 1-Month Formulation	A Randomized, Double-blind, Multi-centre, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Intranasal Esketamine Plus an Oral Antidepressant in Elderly Subjects with Treatment-resistant Depression	An Open-label, Long-term, Safety and Efficacy Study of Intranasal Esketamine in Treatment-resistant Depression (SUSTAIN-2)	A programme of work to develop and evaluate an intervention to promote activity and independence, and prevent falls, for people with early dementia and mild cognitive impairment.	Predictors of progression from mild cognitive impairment to dementia: brain functional network studies	The 4 Mountains Test of spatial memory for diagnosis of early Alzheimer's disease: evaluation of diagnostic specificity	A Psychosocial Therapy to Benefit People with Parkinson's-related Dementia: A Feasibility and Exploratory Pilot Study of Individual Cognitive Stimulation Therapy (INVEST).
First Patient Recruited?	Yes	Yes	Yes	Yes	No	No	Yes
Date of First Patient Recruited	11/11/2016	23/08/2016	01/11/2016	22/09/2016			02/02/2017
Benchmark Met	No	Yes	No	Yes	No	No	
Date Site Invited	15/05/2016	16/05/2016	16/05/2016	04/08/2016	16/03/2016	12/04/2016	26/02/2016
Date Site Selected	08/08/2016	21/06/2016	21/06/2016	04/08/2016	15/08/2016	15/08/2016	26/02/2016
HRA Approval Date	26/07/2016	15/06/2016	15/06/2016	19/08/2016	15/06/2016	15/06/2016	20/09/2016
Date Site Confirmed By Sponsor	09/08/2016	26/04/2016	17/05/2016	19/08/2016	15/08/2016	15/08/2016	16/01/2017
Date Site Confirmed	11/08/2016	09/05/2016	19/05/2016	09/09/2016	09/09/2016	09/09/2016	19/01/2017
Date Site Ready To Start	08/09/2016	22/06/2016	31/08/2016	01/09/2016	12/09/2016	12/09/2016	19/01/2017

A - Permissions delayed/denied	Y	Y	Y		Y	Y	
D - Sponsor Delays					Y	Y	
J - Other			Y	Y			
Comments	HRA approval delay, sponsor concerns on progressing site initiation due to HRA delays as planned study end date in Dec 2016	HRA Approval delay, sponsor concerns on progressing site initiation due to HRA delays	HRA Approval delay and Follow on study so 1st patient can only be recruited to trial after completing preceding trial (IRAS 181387)	Excess Treatment Costs approval delay, but unable to start prior to sponsor planned start date of 01/09/2016 which was achieved	HRA amendment delay in addition of new site and sponsor delay in delivering equipment - ipad with preloaded 4MT test still not delivered as of 31/01/2017 without which recruitment cannot start.	HRA amendment delay in addition of new site and sponsor delay in delivering equipment - ipad with preloaded 4MT test still not delivered as of 31/01/2017 without which recruitment cannot start	
Reasons for delay correspond to:	Neither	Neither	Neither	Neither	Sponsor	Sponsor	

2. Performance in Delivering Commercial Contract Clinical Trials:

(For every commercial contract clinical trial hosted by the NHS provider closed to recruitment in the previous twelve months.)

There was one commercial contract clinical trials hosted by Derbyshire Healthcare NHS Foundation Trust which closed to recruitment in the previous 12 months.

Id	17662
Research Ethics Committee Reference Number	16/SS/0038
Integrated Research Application System Number	198888
Name of Trial	A 52-Week, Open-Label, Prospective, Multi-center, International Study of a Transition to the Paliperidone Palmitate 3-Month Formulation In Patients with Schizophrenia Previously Stabilized on the Paliperidone Palmitate 1-Month Formulation
Target Number Of Patients Agreed?	Range Agreed
Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	3
Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	5
Target Date To Recruit Patients Agreed?	Date Agreed
Date Agreed to recruit target number of patients	31/12/2016
Total Number Of Patients Recruited At The Agreed Target Date	2
Date That The Trial Closed To Recruitment	15/12/2016
Total Number Of Study Participants Recruited	2
Reason For Closure Of Trial	Withdrawn By Sponsor
Comments	2 additional patients pre-booked for screening on 29/12/2016 prior to planned end date of 31/12/2016. Requested by sponsor not to proceed with the 2 additional pre-booked patients as decision made by sponsor to close early on 15/12/2016. Global target likely to be met due to numbers in screening although UK target of 15 not met by 15/12/2016.