National Institute for Health Research Performance in Delivering and Initiating Clinical Research: Q4 2016/17

For further information on these metrics, please see: http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/performance-in-initiating-and-delivering-research/

Performance in Initiating Clinical Research (clinical trials initiated within 12 months)

Id	REC Number	IRAS Number	Submission Type	Name of Trial	First Patient Recruited?	Date of First Patient Recruited	Duration between Date Site Selected and Date Site Confirmed	Duration between Date Site Confirmed and First Patient Recruited	Duration between Date Site Selected and First Patient Recruited	Benchmark Met	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Non-Confirmation Status	Date Site Ready To Start	Reasons for Delay	Comments	Reasons for delay correspond to:
101856	16/NE/0191	202345	HRA Approval	A Phase 2b, double-blind, randomized, placebo-controlled study of RVT-101 in subjects with dementia with Lewy bodies (DLB)	Yes	17/02/2017	103	81	184	No	07/03/2016	17/08/2016	22/08/2016	19/08/2016	28/11/2016	Please Select...	08/12/2016	D - Sponsor Delays G - No patients consented I - Rare diseases	Sponsor green light not given until 08/12/16. Delay with local acute NHS Trust subcontracted for MRIs obtaining ARSAC clearances (NHS delay), Delays in supply of essential trial equipment (Sponsor delay). Patients initially approached did not consent or screen failed. Dementia with Lewy Bodies rare disease.	Both
102079	16/SC/0256	204750	HRA Approval	A Long-Term, Open-Label Extension Study of the Safety and Tolerability of RVT-101 in Subjects with Alzheimer's Disease	Yes	15/03/2017	25	107	132	No	08/06/2017	03/11/2016	07/10/2016	25/10/2016	28/11/2016	Please Select...	15/02/2017	F - No patients seen	Extension study for participants finishing Axovant 3001 AD study. Site initiation visit held 15/02/17. First patient was consented on first date they became eligible for the extension study.	Neither

102246	17/LO/0056	213008	HRA Approval	A multicentre randomised superiority study to compare the effects of an 8-week mindfulness-based intervention versus health education programme on mental health and wellbeing in individuals with Subjective Cognitive Decline (SCD-WELL)	Yes	29/03/2017	1	20	21	Yes	07/09/2016	08/03/2017	08/03/2017	08/03/2017	09/03/2017	Please Select...	09/03/2017			Please Select...

Performance in Delivering Clinical Research (commercial clinical trials closed to recruitment within 12 months)

Id	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	Date That The Trial Closed To Recruitment	Total Number Of Study Participants Recruited	Reason For Closure Of Trial	Comments
20851	13/WA/0271	135084	Pimavanserin in Patients with Alzheimer's Disease Psychosis (ACP-103-019)	Not Available / Not Agreed			Not Available / Not Agreed			27/04/2016	6	Withdrawn By Host	Withdrawn by KCL (Lead site)