



North Staffordshire
Combined Healthcare
NHS Trust

Research & Development Performance in Initiating & Delivering Research April, 2019

This document has been produced in line with guidance provided by the [National Institute for Health Research](#) (NIHR). It details the performance of clinical research trials at North Staffordshire Combined Healthcare, covering the period 1st April 2018 – 31st March 2019

Contact: Louise.Alston@combined.nhs.uk



North Staffordshire
Combined Healthcare

NHS Trust

Introduction

Clinical trial performance at North Staffordshire Combined Healthcare is now measured against two national benchmarks to improve transparency, accuracy and meeting sponsor expectations of all clinical trials hosted by the Trust. NHS providers holding NIHR contracts issued after Autumn 2011 are required to provide and publish, on a quarterly basis, information on the initiation and delivery of clinical trials, including commercial trials. This applies to all clinical trials hosted by the organisation.

Initiation: NHS providers must submit specified information for every clinical trial (regardless of funder or inclusion in NIHR CRN Portfolio) where the Date Site Selected falls within the previous twelve months.

Delivery: NHS providers must submit specified information for every commercial contract clinical trial hosted by the NHS provider closed to recruitment in the previous twelve months.

Performance in Initiating Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Clinical Trial	Date Site Invited	Date Site Selected	Date of HRA Approval	Date Site Confirmed by Sponsor	Date Site Confirmed	Date Site Ready to Start	First Patient Recruited?	Date of First Patient Recruited	Source of Delay in Recruiting First Patient?
NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL

Performance in Delivering Clinical Research

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Clinical Trial	Target Number of Patients Agreed?	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 Agreed Date	Total Number of Study Participants Recruited	Date Trial Closed To Recruitment	Reason for Trial Closure
16/EM/0324	204032	A Phase III Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of Suvorexant (MK-4305) for the treatment of insomnia in alzheimers disease subjects	Number Agreed	4	4	Date Agreed	30/09/2018	0	0	17/09/2018	Recruitment Finished
12/WA/0338	114410	Reducing pathology in Alzheimers disease through angiotensin targeting – The RADAR trial – A phase II, two arm, double-blind, placebo-controlled, randomised trial to evaluate the effect of losartan on brain tissue changes in patients diagnosed with AD	Number Agreed	10	10	Date Agreed	17/05/2018	9	9	17/05/2018	Recruitment Finished
16/YH/0238	199383	A randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia intervention compared to usual care	Number Agreed	13	13	Date Agreed	17/08/2018	12	12	17/08/2018	Recruitment Finished