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 2017 to March 2018- 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.)

Quarter 1 & 3 - There were no eligible studies: Nil Return submitted
Quarter 2 & 4 - There were three eligible studies: See below for details

	Quarter 2	Quarter 4	
Id	110195	118107	118113
TrustId	1133		
Research Ethics Committee Reference Number	16/SC/0435	16/HRA/5525	16/NW/0727
Integrated Research Application System Number	212314	210175	187851
Submission Type	HRA Approval	HRA Approval	HRA Approval
Name of Trial	An Open-label Long-term Extension Safety Study of Intranasal Esketamine inTreatment-resistant Depression Safety and Sustenance of Esketamine Treatment Response With Repeated Doses at Intervals Determined by Symptom Severity (SUSTAIN-3)	MindSHINE 3: A definitive randomised controlled trial investigating two online wellbeing interventions to reduce NHS staff stress	Multi Centre RCT of a group psychOlogical intervention for poStnatal depression in britisH mothers of south asiaN origIn - ROSHNI-2
First Patient Recruited?	Yes	Yes	No

Date of First Patient Recruited	30/08/2017	12/03/2018	
Duration between Date Site Selected and Date Site Confirmed	42	3	41
Duration between Date Site Confirmed and First Patient Recruited	55	11	
Duration between Date Site Selected and First Patient Recruited	97	14	
Benchmark Met	No	Yes	No
Date Site Invited	30/01/2017	29/01/2018	28/11/2017
Date Site Selected	25/05/2017	26/02/2018	29/12/2017
HRA Approval Date	14/03/2017	23/01/2017	06/01/2017
Date Site Confirmed By Sponsor	26/06/2017	03/03/2018	31/01/2018
Date Site Confirmed	06/07/2017	01/03/2018	08/02/2018
Date Site Ready To Start	13/07/2017	07/03/2018	15/02/2018
A - Permissions delayed/denied	No		No
B - Suspended by sponsor	No		No
C - Closed by sponsor	No		No
D - Sponsor Delays	No		No
E - Staff availability issues	No		No
F - No patients seen	No		No
G - No patients consented	No		No
H - Contracting delays	No		No
I - Rare diseases	No		No
J - Other	YES		YES
Reasons for Delay			
Comments	This (sustain-3) study is an extension study so no direct recruitment allowed only rollover subjects from preceding sustain-2 study are eligible for rollover. Site activated by sponsor for sustain-3 on 19/07/2017. Patient booked in to begin required 4 week follow up		Delays in study set up as required to establish that Derby is recruiting site and not Nottingham which is a co-ordinating site in region. Study design includes a two stage recruitment process - 26 women scoring >=10 on PHQ-9 have

	phase of preceding Sustain-2 trial procedures from 01/08/2017 prior to consenting for Sustain-3 trial on 30/08/2017.		already signed consent forms to participate. These women will be required to sign a second consent form following baseline assessments prior to randomisation at which point first patient randomised will be counted as first patient recruited.
Reasons for delay correspond to:	Neither		Neither

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.)

Quarter 1 & 2 - There were two commercial contract clinical trials hosted by Derbyshire Healthcare NHS Foundation Trust which closed to recruitment in the previous 12 months.

Quarter 3 & 4 - Nil returns were submitted

	Quarter 1	Quarter 2	Quarter 3 & 4
Id	24797	24798	NIL
TrustId	1133	1133	
Research Ethics Committee Reference Number	15/SC/0432	15/SC/0434	
Integrated Research Application System Number	181387	181955	
Name of Trial	A Randomized, Double-blind, Multicenter, 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)	
Target Number Of Patients Agreed?	Range Agreed	Number Agreed	
Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number)	1	1	
Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number)	3	1	
Target Date To Recruit Patients Agreed?	Date Agreed	Not Available / Not Agreed	
Date Agreed to recruit target number of patients	31/07/2017		

Total Number Of Patients Recruited At The Agreed Target Date	1		
Date That The Trial Closed To Recruitment	10/05/2017	30/08/2017	
Total Number Of Study Participants Recruited	2	1	
Reason For Closure Of Trial	Withdrawn By Sponsor	Recruitment Finished	
Comments	15/03/2017 UK country commitments reduced and individual site targets also reduced. Trial then subsequently withdrawn by sponsor on 10/05/2017 and closed to further recruitment. 2 participants recruited but only 1 participant remained on trial prior to recruitment end date in May 2017.	This is a follow on study so 1st patient can only be recruited to trial after completing preceding trial (TRANSFORM IRAS 181387). So no recruitment date/target agreed. Only 1 participant recruited to the preceding trial and hence eligible for this follow on trial. This was a non-recruiting trial so no date when trial closed to recruitment but the date that the participant consented to roll over to extension trial (SUSTAIN-3 IRAS 212314) is given as the trial end date.	