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 for clinical trial initiation; and the recruitment to time and target for commercial contract clinical trials.

Report period: covering April 2018 to March 2019 - 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** - There were no new eligible studies: however previous study reported in 2017-18 Quarter 4 was updated with date first patient recruited
^Quarter 2 - This study Id 132336 was previously submitted in Q2 as Id 128703
Quarter 4 – There were no new eligible studies to report.

	Q1*	Q3			
Id	**123606 (previously 118113)**	**132336^ (previously 128703)**	**132348**	**132355**	**132379**
Research Ethics Committee Reference Number	16/NW/0727	18/YH/0059	18/WM/0281	17/YH/0405	17/EE/0454
Integrated Research Application System Number	187851	236099	225736	216780	233276
Submission Type	HRA Approval	HRA Approval	HRA Approval	HRA Approval	HRA Approval

	Q1*	Q3			
Id	**123606 (previously 118113)**	**132336^ (previously 128703)**	**132348**	**132355**	**132379**
Name of Trial	Multi Centre RCT of a group psychOlogical intervention for poStnatal depression in britisH mothers of south asiaN origIn - ROSHNI-2	Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment - PrAISED2	Promoting Independence in Dementia (PRIDE): A Feasibility Randomised Controlled Trial	Adapting individual Cognitive Stimulation Therapy (iCST) for delivery by a web-application	Individual Placement and Support (IPS) for people with drug and alcohol use disorder (IPS-AD Trial). A pragmatic, multi-centre, parallel group, randomised controlled trial of specialist versus standard employment seeking support
First Participant Recruited?	Yes	Yes	Yes	Yes	Yes
Date of First Participant Recruited	25/06/2018	15/10/2018	17/12/2018	21/11/2018	16/05/2018
Duration between Date Site Selected and Date Site Confirmed	41	24	38	5	5
Duration between Date Site Confirmed and First Participant Recruited	137	24	14	22	-219
Duration between Date Site Selected and First Participant Recruited	**178**	48	52	27	-214

	Q1*	Q3			
Id	**123606 (previously 118113)**	**132336^ (previously 128703)**	**132348**	**132355**	**132379**
Date Site Invited	28/11/2017	18/12/2017	26/10/2018	25/04/2018	04/12/2018
Date Site Selected	29/12/2017	28/08/2018	26/10/2018	25/10/2018	16/12/2018
HRA Approval Date	06/01/2017	09/04/2018	24/10/2018	09/03/2018	15/01/2018
Date Site Confirmed By Sponsor	31/01/2018	10/09/2018	26/10/2018	25/10/2018	23/03/2018
Date Site Confirmed	08/02/2018	21/09/2018	03/12/2018	30/10/2018	21/12/2018
Date Site Ready To Start	15/02/2018	24/09/2018	07/12/2018	30/10/2018	09/05/2018
A - Permissions delayed/denied	No				
B - Suspended by sponsor	No				
C - Closed by sponsor	No				
D - Sponsor Delays	No				
E - Staff availability issues	No				
F - No patients seen	No				

	Q1*	Q3			
Id	**123606 (previously 118113)**	**132336^ (previously 128703)**	**132348**	**132355**	**132379**
G - No patients consented	No				
H - Contracting delays	No				
I - Rare diseases	No				
J - Other	YES				
Comments	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 already signed consent forms to participate (1Apr18). 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 which was 25/06/2018.				Date first participant recruited is earlier than Date Site Confirmed. This is because retrospective confirmation of capacity and capability provided as R&D informed retrospectively. Contract signed by Trust on 23/03/2018 which remains effective date. Service provision/Trial delivery subcontracted to third party - Intuitive Thinking Skills working with Derbyshire Recovery Partnership. Initial liaison between Trust local service manager, Intuitive Thinking Skills & Sponsor before R&D notified.
Reasons for delay correspond to:	Neither	Not Applicable	Not Applicable	Not Applicable	Not Applicable

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 - Nil return submitted

Quarter 2 – Nil return submitted

Quarter 3 – Nil return submitted

Quarter 4 – Nil return submitted