Performance information on the initiation and delivery of clinical research

The Government wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research. The aim is to increase the number of participants who have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research. Providers of NHS services are required to publish information on recruitment to clinical trials and delivery to time and to target for commercial clinical trials.

Report period: covering April 2019 to December 2019 - End of Quarter 3, 2019-20

1. Performance in initiating Clinical Trials:

(For **every** clinical trial (regardless of funder or inclusion in NIHR CRN Portfolio) where the **Date Site Selected falls within the previous twelve months)**

Quarter 1 - There were no eligible studies: **Nil Returns Submitted**

Quarter 2 - There were no eligible studies: **Nil return submitted**

Quarter 3 - There was one eligible study.

	Q3
Id	**157669**
Research Ethics Committee Reference Number	19/NE/0233
Integrated Research Application System Number	239794
Submission Type	HRA Approval
Name of Trial	A randomised, double-blind, placebo controlled trial of pramipexole in addition to mood stabilisers for patients with treatment resistant bipolar depression. (PAX-BD)

	Q3
Id	**157669**
First Participant Recruited?	No
Date of First Participant Recruited	
Duration between Date Site Selected and Date Site Confirmed	38
Duration between Date Site Confirmed and First Participant Recruited	
Duration between Date Site Selected and First Participant Recruited	
Date Site Invited	18/07/2019
Date Site Selected	12/11/2019
HRA Approval Date	05/09/2019
Date Site Confirmed By Sponsor	20/12/2019
Date Site Confirmed	20/12/2019
Date Site Ready To Start	20/12/2019
A - Permissions delayed/denied	No
B - Suspended by sponsor	No

	Q3
Id	**157669**
C - Closed by sponsor	No
D - Sponsor Delays	No
E - Staff availability issues	No
F - No patients seen	No
G - No patients consented	No
H - Contracting delays	No
I - Rare diseases	No
J - Other	YES
Comments	Challenging combination of eligibility criteria, some potentially eligible participants have subsequently failed screening
Reasons for delay correspond to:	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 - There were no eligible studies: **Nil return submitted**

Quarter 2 - There were no eligible studies: **Nil return submitted**

Quarter 3 - There were no eligible studies: **Nil return submitted**