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 March 2020 - End of Quarter 4, 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.

Quarter 4 - There was one new eligible study and one study carried forward from Q3 comments updated.

	Q3 & Q4	Q4
Id	**157669 & 165007**	**165008**
Research Ethics Committee Reference Number	19/NE/0233	19/EM/0326
Integrated Research Application System Number	239794	249015
Submission Type	HRA Approval	HRA Approval

	Q3 & Q4	Q4
Id	**157669 & 165007**	**165008**
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)	NEON (Narrative Experiences Online) study: trials of an online intervention. NEON Trial, NEON-O Trial. NEON-C Trial
First Participant Recruited?	No	Yes
Date of First Participant Recruited		16/03/2020
Duration between Date Site Selected and Date Site Confirmed	38	7
Duration between Date Site Confirmed and First Participant Recruited		7
Duration between Date Site Selected and First Participant Recruited		14
Date Site Invited	18/07/2019	02/03/2020
Date Site Selected	12/11/2019	02/03/2020
HRA Approval Date	05/09/2019	13/12/2019
Date Site Confirmed By Sponsor	20/12/2019	02/03/2020
Date Site Confirmed	20/12/2019	09/03/2020
Date Site Ready To Start	20/12/2019	09/03/2020
A - Permissions delayed/denied	No	No

	Q3 & Q4	Q4
Id	**157669 & 165007**	**165008**
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	No
Comments	Challenging combination of eligibility criteria, some potentially eligible participants have subsequently failed screening. **Q4 Update:** Study paused in March 2020 due to COVID-19 Emergency Planning measures and has not yet been restarted. A decision to restart or not is expected by 30/10/2020.	
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**

Quarter 4 - There were no eligible studies: **Nil return submitted**