

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 2020 to March 2021 - End of Quarter 4, 2020-21

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 new eligible studies: One study carried forward from 2019-20 (paused and not yet restarted).

Quarter 2 - There was one new eligible study added

Quarter 3 -There was one new eligible study added. One study from Quarter 2 updated with first participant recruited date

Quarter 4 - There were no new eligible studies

	2019-20 Q3 & Q4 / 2020-21 Q1 & Q2	Q2 & Q3	Q3
Id	157669 & 165007 & 165009 & 165011	165013 & 176807	178292
Research Ethics Committee Reference Number	19/NE/0233	18/WA/0209	20/EM/0038
Integrated Research Application System Number	239794	238724	272551
Name of Trial	(PAX-BD) - A randomised, double-blind, placebo controlled trial of pramipexole in addition to mood stabilisers for patients with treatment resistant bipolar depression.	PATHFINDER - Problem Adaptation Therapy for individuals with mild to moderate dementia and depression	Developing an evidence base for the use of Art Psychotherapy within a perinatal mental health service

	2019-20 Q3 & Q4 / 2020-21 Q1 & Q2	Q2 & Q3	Q3
Id	157669 & 165007 & 165009 & 165011	165013 & 176807	178292
First Participant Recruited?	No	Yes	No
Date of First Participant Recruited		13/11/2020	
Duration between Date Site Selected and Date Site Confirmed	38	66	70
Duration between Date Site Confirmed and First Participant Recruited		42	
Duration between Date Site Selected and First Participant Recruited		108	
Date Site Invited	18/07/2019	29/01/2020	24/09/2019
Date Site Selected	12/11/2019	28/07/2020	30/09/2020
HRA Approval Date	05/09/2019	25/06/2018	24/03/2020
Date Site Confirmed By Sponsor	20/12/2019	13/08/2020	17/11/2020
Date Site Confirmed	20/12/2019	02/10/2020	09/12/2020
Date Site Ready To Start	20/12/2019	25/09/2020	11/05/2021
A - Permissions delayed/denied	No	Yes	Yes
B - Suspended by sponsor	No	No	No
C - Closed by sponsor	No	No	No

	2019-20 Q3 & Q4 / 2020-21 Q1 & Q2	Q2 & Q3	Q3
Id	157669 & 165007 & 165009 & 165011	165013 & 176807	178292
D - Sponsor Delays	No	No	No
E - Staff availability issues	No	No	No
F - No patients seen	No	No	No
G - No patients consented	No	No	No
H - Contracting delays	No	No	No
I - Rare diseases	No	No	No
J – Other	YES	YES	YES
Comments	<p>Challenging combination of eligibility criteria, some potentially eligible participants have subsequently failed screening.</p> <p>Q1&2 Update: Study paused in March 2020 due to COVID-19 Emergency Planning measures. Restart confirmed on 17/12/2020.</p> <p>Q3&Q4 Update: Paused again during second lockdown period. Contract amendment requested and signed by site 20/03/2021. Substantial Amendment 11 received and capacity and capability re-confirmed on 05/05/2021</p>	<p>Study setup paused in March 2020 due to COVID-19 Emergency Planning. Restarted in September 2020 following study amendments. Participant recruitment affected by impact of pandemic on clinical service delivery and consequent lower numbers of eligible participants.</p>	<p>PhD student research affected by pandemic as clinical services unable to operate business as usual. Study setup affected by pauses in March and December 2020.</p>
Reasons for delay correspond to:	Neither	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 - 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**