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 reporting window 01 April 2021 to 31 March 2022 - End of Quarter 4, 2021-22

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 was one new eligible study. Two studies carried forward from 2020-21 as within 01Jul20-30Jun21 reporting window.
Quarter 2 - There was one new eligible study. One study carried forward from Q1 as within 01Oct20-30Sep21 reporting window.
Quarter 3 – There were no new eligible studies. One study carried forward from Q2 as within 01Jan21-31Dec21 reporting window.
Quarter 4 - There was one new eligible study. One study carried forward from Q3 as within 01Apr21-31March22 reporting window.

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q4 2021-22	Q4 2021-22
Id	183305	183306	187452	201520	201521
Previous Ids	20-21: Q2 165013 & Q3 176807	20-21: Q3: 178292	Not Applicable	21-22 Q1: 183307 & Q2 187451 & Q3 193889	Not Applicable
Research Ethics Committee Reference Number	18/WA/0209	20/EM/0038	1821/WM/00043307	20/EE/0217	20/EM/0216
Integrated Research Application System Number	238724	272551	289982	283342	279574
Name of Trial	PATHFINDER - Problem Adaptation Therapy for individuals	Developing an evidence base for the use of Art Psychotherapy within a	Achieving Quality and Effectiveness in Dementia Using Crisis Teams	Double-Blind, Randomized, Parallel-Group Study with	Antidepressant for the prevention of DEPression

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Id	183305	183306	187452	201520	201521
	with mild to moderate dementia and depression	perinatal mental health service	(AQUEDUCT): A Randomised Controlled Trial of a Resource Kit for Teams Managing Crisis in Dementia	Quetiapine Extended Release as Comparator to Evaluate the efficacy and safety of Seltorexant 20mg as Adjunctive Therapy to Antidepressants in Adults and Elderly Patients with Major Depressive Disorder with Insomnia Symptoms Who Have Responded Inadequately to Antidepressant Therapy	following first episode Psychosis trial
First Participant Recruited?	Yes	Yes	Yes	No	No
Date of First Participant Recruited	13/11/2020	16/09/2021	27/09/2021		
Duration between Date Site Selected and Date Site Confirmed	66	70	40	22	43
Duration between Date Site Confirmed and First Participant Recruited	42	281	7		
Duration between Date Site Selected and First Participant Recruited	108	351	47		
Date Site Invited	29/01/2020	24/09/2019	24/03/2021	11/05/2020	01/02/2022
Date Site Selected	28/07/2020	30/09/2020	11/08/2021	27/04/2021	15/02/2022

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q4 2021-22	Q4 2021-22
Id	183305	183306	187452	201520	201521
HRA Approval Date	25/06/2018	24/03/2020	09/03/2021	10/06/2021	30/11/2020
Date Site Confirmed By Sponsor	13/08/2020	17/11/2020	11/08/2021	27/04/2021	30/03/2022
Date Site Confirmed	02/10/2020	09/12/2020	20/09/2021	19/05/2021	30/03/2022
Date Site Ready To Start	25/09/2020	11/05/2021	27/09/2021	13/09/2021	07/04/2022
A - Permissions delayed/denied	YES	YES		YES	YES
B - Suspended by sponsor	No	No		No	No
C - Closed by sponsor	No	No		No	No
D - Sponsor Delays	No	No		YES	No
E - Staff availability issues	No	No		YES	No
F - No patients seen	No	No		No	No
G - No patients consented	No	No		No	YES
H - Contracting delays	No	No		No	YES
I - Rare diseases	No	No		No	No
J – Other	YES	YES		No	No

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q4 2021-22	Q4 2021-22
Id	183305	183306	187452	201520	201521
Comments	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.	Update Q2: first participant recruit date updated on this report but unable to submit for online Q2 return due to date site selected falling out of reporting window. 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 lockdowns. Since 12/05/2021 participant recruitment has started but all invited so far have either declined or not yet confirmed interest to participate.	Site randomised to intervention arm. First staff (clinicians) participants recruited. Clinicians are required to complete the best practice toolkit after which the go head to recruit patients and carers will be given.	**Q4:** One potentially eligible participant attended screening visit but failed screening due to blood results and will be re-screened in 3 months. Pre-screening for eligible participants continues including via the Acurian database. The last amendment increased the maximum duration of stable antidepressant therapy to 18 months (from 12) and increased the length of the current depressive episode to ≤24 months (from 18) and participants falling within this range continues to be the key challenge. **Q3:** Pre-screening of potentially eligible participants have continued since site activation on 13/09/2021. Substantial amendment 3 implemented in Dec 2021 which clarifies and improves identification	Delay in contract review at site. 10 eligible patients Identified. 1 declined, 1 has asked for time to consider and 1 not offered on clinical advice due to clinical complexities. All other potential participants in line with study protocol are awaiting care coordinators to share study information when next they are planned to see their patients. No eligible patients have consented yet.

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q4 2021-22	Q4 2021-22
Id	183305	183306	187452	201520	201521
				of eligible participants. No eligible participants have consented yet. **Q2:** Screening of participants commenced following site activation (green light) on 13/09/2021. No eligible participants have consented yet. **Q1**: Green light not received since Site Initiation Visit on 20/05/2021, site not activated. Some delay in completing training at site. 10/06/2021 substantial amendment 1 approval confirmed by sponsor. 09/07/2021 continuing capacity and capability confirmed by site for amendment 1 and requested to proceed with contract amendment signatures. Some delay in reviewing amendment 1 at site due to competing demands.	

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Reasons for delay correspond to:	Neither	Neither	Not Applicable	Both	NHS Provider

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**