

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 October 2020 to 30 September 2021 - End of Quarter 2, 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**.

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q2 2021-22
Id	183305	183306	187451	187452
Previous Ids	20-21: Q2 165013 & Q3 176807	20-21: Q3: 178292	21-22 Q1: 183307	Not Applicable
Research Ethics Committee Reference Number	18/WA/0209	20/EM/0038	20/EE/0217	1821/WM/00043307
Integrated Research Application System Number	238724	272551	283342	289982
Name of Trial	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	Double-Blind, Randomized, Parallel-Group Study with Quetiapine Extended Release as Comparator to Evaluate the efficacy and safety of Seltorexant	Achieving Quality and Effectiveness in Dementia Using Crisis Teams (AQUEDUCT): A Randomised Controlled Trial of a Resource

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			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	Kit for Teams Managing Crisis in Dementia
First Participant Recruited?	Yes	Yes	No	Yes
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	22	40
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	11/05/2020	24/03/2021
Date Site Selected	28/07/2020	30/09/2020	27/04/2021	11/08/2021
HRA Approval Date	25/06/2018	24/03/2020	10/06/2021	09/03/2021
Date Site Confirmed By Sponsor	13/08/2020	17/11/2020	27/04/2021	11/08/2021
Date Site Confirmed	02/10/2020	09/12/2020	19/05/2021	20/09/2021

Reporting Quarter	Q1 2021-22	Q1 2021-22	Q2 2021-22	Q2 2021-22
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Date Site Ready To Start	25/09/2020	11/05/2021	13/09/2021	27/09/2021
A - Permissions delayed/denied	Yes	Yes	Yes	
B - Suspended by sponsor	No	No	No	
C - Closed by sponsor	No	No	No	
D - Sponsor Delays	No	No	YES	
E - Staff availability issues	No	No	YES	
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	No	
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	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.	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	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.

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	delivery and consequent lower numbers of eligible participants.	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.	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.	
Reasons for delay correspond to:	Neither	Neither	Both	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 - There were no eligible studies: **Nil return submitted**

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