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 2021 to 30 September 2022 - End of Quarter 2, 2022-23

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 two new eligible studies. Two studies carried forward from 2021-22 as within 01Jul21-30Jun22 reporting window.
Quarter 2 – There was one new eligible study.

Reporting Quarter	Q1 2022-23	Q1 2021-22	Q1 2022-23	Q1 2022-23	Q2 2022-23
Id	Out of Q1 reporting window*	22-23 Q1: 205679	22-23 Q1: 205694	22-23 Q1: 205791	211111
Previous Ids	21-22 Q1: 183307 & Q2 187451 & Q3 193889 & Q4 201520	21-22 Q4: 201521	Not applicable	Not applicable	Not applicable
Research Ethics Committee Reference Number	20/EE/0217	20/EM/0216	22/WA/0031	21/EE/0204	19/NW/0316
Integrated Research Application System Number	283342	279574	307766	301794	264686

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Id	**Out of Q1 reporting window***	22-23 Q1: 205679	22-23 Q1: 205694	22-23 Q1: 205791	211111
Name of Trial	Double-Blind, Randomized, Parallel-Group Study with 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	Antidepressant for the prevention of DEPression following first episode Psychosis trial	Glasses in Classes Pathfinders	The Self-harm, Assessment, Formulation, Engagement Trial of Psychodynamic Interpersonal Therapy (SAFE-PIT)	A Cluster Randomised Controlled Trial of a Ward-Based Intervention to Improve Access to Psychologically-Informed Care and Psychological Therapy for Mental Health In-Patients (TULIPS)
First Participant Recruited?	No	Yes	Yes - date unavailable	Yes	Yes
Date of First Participant Recruited		01/07/2022		17/06/2022	15/08/2022
Duration between Date Site Selected and Date Site Confirmed	22	43	98	26	18
Duration between Date Site Confirmed and First Participant Recruited		93		18	13

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Duration between Date Site Selected and First Participant Recruited		136		44	31
Date Site Invited	11/05/2020	01/02/2022	02/03/2022	04/05/2022	15/07/2022
Date Site Selected	27/04/2021	15/02/2022	02/03/2022	04/05/2022	15/07/2022
HRA Approval Date	10/06/2021	30/11/2020	16/02/2022	14/10/2021	18/07/2019
Date Site Confirmed By Sponsor	27/04/2021	30/03/2022	02/03/2022	10/05/2022	29/06/2022
Date Site Confirmed	19/05/2021	30/03/2022	08/06/2022	30/05/2022	02/08/2022
Date Site Ready To Start	13/09/2021	07/04/2022	08/06/2022	01/06/2022	08/08/2022
A - Permissions delayed/denied	YES	YES	No	No	
B - Suspended by sponsor	No	No	No	No	
C - Closed by sponsor	No	No	No	No	
D - Sponsor Delays	YES	No	No	No	
E - Staff availability issues	YES	No	No	No	

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F - No patients seen	No	No	No	No	
G - No patients consented	No	No	No	No	
H - Contracting delays	No	YES	No	No	
I - Rare diseases	No	No	No	No	
J – Other	No	No	YES	No	
Comments	***This study is not eligible for reporting in Q2 but an update is provided for the website.** **Q2 2022-23:** First UK participant recruited at DHCFT on 06/07/2022. **Q1 2022-23:** We have a participant who has consented to the trial and is going through the screening process. We hope they will be randomised during the 1st week in August '22.	**Q1 2022-23:** Eligibility criteria broadened following substantial amendment 4 on 10/06/2022 and variation to contract signed 16/06/2022. First participant consented to participate on 01/07/2022. Another screening visit booked in for second potential participant on 02/08/2022. We have pre-screened over 200 referrals of which around 30 patients are eligible and will be invited to consider participation through their care coordinators.	02/03/2022 R&D informed of the study by the study Project Manager. Following assess and arrange review / discussions it was identified that research activities at site had already commenced since Jan 2022. Confirmation of Capacity and Capability issued retrospectively by site on 08/06/2022. This study provides a free second pair of glasses kept at school for Reception children with failed vision screening which is routinely carried out by NHS services. Study is	No delays	No delays

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	We are continuing with pre-screening the Acurian database (self-refer) and have recently extended the geographical radius. We are also in the process of opening a General Practice Participant Identification Centre (PIC) site. **Q4 2021-22**: 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)	**Q4 2021-22**: 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.	funded by Dept. of Education.		

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	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 2021-22**: 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 of eligible participants. No eligible participants have consented yet. **Q2 2021-22**: Screening of participants commenced following site activation (green light) on 13/09/2021. No eligible participants have consented yet. **Q1 2021-22**: Green light not received since Site				

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	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.				
Reasons for delay correspond to:	Both	NHS Provider	Both	Not Applicable	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**