## 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 July 2021 to 30 June 2022 - End of Quarter 1, 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.

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

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|---|---|---|---|---|
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| | Adults and Elderly Patients with Major Depressive Disorder with Insomnia Symptoms Who Have Responded Inadequately to Antidepressant Therapy | | | |
| First Participant Recruited? | No | Yes | Yes - date unavailable | Yes |
| Date of First Participant Recruited | | 01/07/2022 | | 17/06/2022 |
| Duration between Date Site Selected and Date Site Confirmed | 22 | 43 | 98 | 26 |
| Duration between Date Site Confirmed and First Participant Recruited | | 93 | | 18 |
| Duration between Date Site Selected and First Participant Recruited | | 136 | | 44 |
| Date Site Invited | 11/05/2020 | 01/02/2022 | 02/03/2022 | 04/05/2022 |
| Date Site Selected | 27/04/2021 | 15/02/2022 | 02/03/2022 | 04/05/2022 |
| HRA Approval Date | 10/06/2021 | 30/11/2020 | 16/02/2022 | 14/10/2021 |
| Date Site Confirmed By Sponsor | 27/04/2021 | 30/03/2022 | 02/03/2022 | 10/05/2022 |
| Date Site Confirmed | 19/05/2021 | 30/03/2022 | 08/06/2022 | 30/05/2022 |
| Date Site Ready To Start | 13/09/2021 | 07/04/2022 | 08/06/2022 | 01/06/2022 |

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|---|---|---|---|---|
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| 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 |
| 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 Q1 but an update is provided for the website.**<br><br>**Q1 2022-23:** We have a participant who has consented to the trial and is going through the screening process. We hope | **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 | 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 | No delays |

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|---|---|---|---|---|
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| | they will be randomised during the 1st week in August '22. We are continuing with pre-screening the Acurian database (self-refer) and have recently extended the geographical radius.<br><br>We are also in the process of opening a General Practice Participant Identification Centre (PIC) site.<br><br>**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) 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. | 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.<br><br>**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. | 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 funded by Dept. of Education. | |

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| | **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.<br><br>**Q2 2021-22**: Screening of participants commenced following site activation (green light) on 13/09/2021. No eligible participants have consented yet.<br><br>**Q1 2021-22**: 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 | | | |

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| | reviewing amendment 1 at site due to competing demands. | | | |
| **Reasons for delay correspond to:** | Both | NHS Provider | 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**