

Performance in Initiating and Delivering Clinical Research – NCH&C Q2 2018/19

The Department of Health and Social Care is committed to improving clinical trial performance and reducing site set up and participant recruitment time. The aim is to increase the number of patients who have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research.

The Government's Plan for Growth, published in March 2011, announced the transformation of incentives at local level for efficiency in initiation and delivery of clinical research.

As part of this incentive, the Department of Health requires, via the new National Institute for Health Research (NIHR) contracts with providers of NHS services, the publication on a quarterly basis of information regarding recruitment to clinical trials and the recruitment to time and target for commercial contract clinical trials.

As of Quarter 1 2018-19, recruitment to clinical trials will no longer be assessed with a 70 day benchmark for the duration between Date Site Selected and date of First Patient Recruitment and there no longer be financial penalties for poor performance. A renewed focus is placed on publication of transparent and accurate performance data to better meets the needs of organisations working to improve timelines and industry partners seeking to use such data in site selection. Trusts will still be required to report in their submissions any instances perceived to be a delay in the set-up/recruitment of the trial giving a reason to the delay.

For **Performance in Initiating Clinical Research**, NHS providers must publish the following information:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- The date the site was invited
- The date the site was selected
- The HRA Approval date
- The date the site was confirmed by the sponsor
- The date the site was confirmed
- The date when the site is ready to start
- The date of the recruitment of first patient, and
- The source of the delay in recruiting the first patient into a trial.

Plus, in the event that a trial initiation did not proceed to confirmation:

- The non-confirmation status.

NHS providers are also required to publish the following information regarding commercial contract clinical trials for **Performance in Delivering** Clinical Research:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial

- Whether or not a target number of patients was agreed
- The minimum number of patients agreed to be recruited (if a range has been agreed; this will be the same as the maximum if a fixed number has been agreed)
- The maximum number of patients agreed to be recruited (if a range has been agreed; this will be the same as the minimum if a fixed number has been agreed)
- Whether or not a target date to recruit patients was agreed
- The date agreed to recruit the target number of patients
- The total number of patients recruited at the agreed target date
- The total number of study participants recruited
- The date that the trial closed to recruitment
- The reason for the closure of the trial.

Norfolk Community Health & Care NHS Trust published this data for the first time in Q3 2014/15

Table 1 - Performance in Initiating Research Q2 2018/19

- HRA Approval given:

Name of Trial	Research Ethics Committee Reference Number	IRAS number	Date Site Invited	Date site selected	HRA Approval date	Date site confirmed by Sponsor	Date site confirmed	Date Site Ready to Start	Date of Recruitment 1st Patient	The Source of Delay in recruiting the first patient into a trial
Is it possible to develop a complex intervention to improve the outcome of falls in people with dementia (Work package 4)? DIFRIDWP4	17/NE/0297	227451	28/11/2017	14/12/2017	08/11/2017	22/12/2017	22/12/2017	15/03/2018	19/04/2018	Sponsor
RETurn to work After stroKE (RETAKE) Early vocational rehabilitation compared with usual care for stroke survivors: an individually randomised controlled multi-centre pragmatic trial with embedded economic and process evaluations	18/EM/0019	234874	28/09/2017	01/03/2018	21/02/2018	01/03/2018	14/03/2018	08/05/2018	07/06/2018	Sponsor

Name of Trial	Research Ethics Committee Reference Number	IRAS number	Date Site Invited	Date site selected	HRA Approval date	Date site confirmed by Sponsor	Date site confirmed	Date Site Ready to Start	Date of Recruitment 1st Patient	The Source of Delay in recruiting the first patient into a trial
Stimulation of the Tibial Nerve – A randomised trial for urinary problems associated with Parkinson's - The STARTUP trial	18/ES/0042	241253	20/08/2018	20/08/2018	04/07/2018	22/08/2018	30/08/2018	21/09/2018	Not recruited to date	n/a
A comparison of the effects of two isometric calf muscle exercise(s) on pain and function in patients with chronic, mid-portion Achilles tendinopathy.	18/NS/0094	245669	10/05/2018	26/09/2018	27/09/2018	Not confirmed yet				

- For this Q2 2018/19 there are no commercial clinical trials that fulfil the criteria for the PID reporting and there is a nil return for Performance in Delivering