Performance in Initiating and Delivering Clinical Research – NCH&C Q4 2015/16

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 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 incentivation, 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: the 70-day benchmark for clinical trial initiation; and the recruitment to time and target for commercial contract clinical trials.

Providers of NHS services are required to publish the following information for **Initiating Clinical Research** (i.e. the 70-day benchmark) on a publicly available part of their website:

- The name of the trial;
- The Research Ethics Committee reference number;
- The date of receipt of a Valid Research Application;
- The date of the recruitment of first patient; and
- Where the benchmark has not been achieved for a particular clinical trial, the reason for not doing so.

From Q4 2015-16, for trials which are subject to HRA approval rather than NHS approval, 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 study was initiated (HRA submission date)
- 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
- Reasons for 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.

Providers of NHS services are also required to publish the following information regarding commercial contract clinical trials, to meet the transparency commitment for delivering clinical research to time and target on a publicly available part of their website:

From Q4 2015-16, providers are required to publish the follow information 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 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 Q4 2015/16

Name of Trial	Research Ethics Committee Reference Number	Date of receipt of a Valid Research Application	Date of Recruitment of First Patient	70 day Benchmark Met?	Reasons for not meeting benchmark
OCS care: A pilot study for developing and evaluating a care pathway for cognitive problems after stroke	12/WM/0335	22/11/2015	n/a	No	Delays due to several factors - suspension of recruitment by Sponsor while substantial amendments were being approved and failure to inform NCH&C when recruitment was reopened; - the study chief investigator passed away; - the Sponsor is also requesting GCP training for all OT staff involved in the study which is not usual for a study of this type and is resulting in delays.
A multi-centre randomised controlled trial to assess the effectiveness and cost effectiveness of a home-based self-management standing frame programme plus usual care versus usual care in people with progressive multiple sclerosis (MS) who have severely impaired balance and mobility (SUMS)	15/SW/0088	15/05/2015	04/11/2015	No	Non-model contract agreement and complex contracting requirements involving multiple parties involved in delivering the study. Contractual delays incurred on the Sponsor and NCH&C side.

Table 2 - Performance in Delivering Clinical Research – Q4 2015/16

Name of Trial	Research Ethics Committee Reference Number	Target Number of Patients	Date agreed to recruit target number of patients	Trial Status	Target Met	Comments
An exploratory, 12 week, randomised, partially double-blinded, placebo-controlled, parallel group trial to explore the effects of once daily treatments of orally inhaled tiotropium + olodaterol fixed dose combination or tiotropium (both delivered by the Respimat® inhaler), supervised exercise training and behaviour modification on exercise capacity and physical activity in patients with Chronic Obstructive Pulmonary Disease (COPD) [PHYSACTO(TM)]	14/EM/0101	No target needed	N/A	Closed – in Follow-up (at NNUH)	N/A	NCH&C is only involved in delivering part of the intervention and it is not involved in recruitment