Performance in Initiating and Delivering Clinical Research – NCH&C Q4 2014/15

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 incentivisation, 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.

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:

- The name of the trial;
- The Research Ethics Committee reference number;
- The target number of patients it has agreed to recruit to that trial;
- The date by which it has agreed to recruit the target number of patients;
- The trial status: e.g. ongoing or finished; and
- If trial recruitment has finished, whether or not the agreed target number of patients was recruited within the agreed time.

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

Table 1 - Performance in Initiating Research Q4 2014/15

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
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	04/06/2014	N/A		NCH&C is only involved in delivering part of the intervention and it is not involved in recruitment
A single blind study comparing the efficacy of Glycopyrronium and Hyoscine on drooling in children with neurodisability	13/NE/0078	09/07/2014	24/10/2014	No	The study needed joint approval from NCH&C and the acute Trust as Pharmacy at the hospital was involved. The hospital approval was not granted until 16.10.14. There were some issues around staffing shortage at the acute Trust which held the approval, also a new PI had to be identified. Therefore a contract agreement between NHC&C and the acute Trust was not in place until 16.09.14
Neurophysiological investigation of the effects of SaeboFlex training on upper limb recovery in people early after stroke.	14/EE/0174	28/04/2014	No patients recruited		REC approval was not obtained until 30/07/2014 due to issues with recruitment strategy and study design. Because it is a time limited student project they are unable to pursue recruitment and the study has closed down.
Pressure Relieving Support Surfaces: A Randomised Evaluation 2	13/YH/0066	22/07/2014	06/11/2014	No	Did not have the recruiting

					nurse in post until end of September and the study training was not until 27th October. Also the PI left and another had to be identified
Cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke (Big CACTUS)	13/YH/0377	09/12/2014	03/02/15	Yes	

Table 2 - Performance in Delivering Clinical Research – Q4 2014/15

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		Open at NNUH	N/A	NCH&C is only involved in delivering part of the intervention and it is not involved in recruitment