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NHS Nottinghamshire County CCGs Research Activity Report 2012/2013

Research Management and Governance

June, 2013

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Research Activity Report 2012/2013

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1. Overview

In order to performance manage and evaluate the work that is undertaken within NHS Nottinghamshire County CCGs, Nottinghamshire Healthcare NHS Trust (NHCT) have adopted Key Performance Indicators (KPIs) which allow us to link our activities to 'process and outcomes-based' metrics. We monitor research activity within NHS Nottinghamshire County CCGs so that we can capture these measurements on an ongoing basis along the timeline of the project. All NHS Trusts have a duty, through the NHS Constitution, to promote opportunities for patients to take part in clinical research studies. The NIHR provides support for the delivery clinical research trials in the NHS in England, and there are now new measures of how individual Trusts are delivering on that duty across the different therapy areas.

The RM&G team undertakes the research management and governance on behalf of Nottinghamshire Healthcare NHS Trust, County Health Partnerships, Bassetlaw Health Partnerships, NHS Nottingham City CCGs, NHS Nottinghamshire County CCGs and Nottingham CityCare Partnership. This arrangement has ensured the standardisation of RM&G processes across Nottingham and Nottinghamshire, reducing duplication and fitting well against the Trent research network structure.

2. Introduction

As a research led organisation, NHCT encourages NHS staff, service users and students to participate in research and values the integrity and engagement brought by clinical researchers of all types to help us make discoveries that matter to people's health and wellbeing, whilst hopefully addressing some of the fundamental health challenges of our time.

During 2012/2013, Nottinghamshire County CCGs have sustained commitment to research in a changing and challenging environment. Key accomplishments during this period include:

- Recruiting 525 participants to 36 Portfolio adopted studies and 5 Non- Portfolio studies
- Meeting 30 day targets for Date Local Complete Document Set Validated to date of NHS Permission and date SSI form submitted to date of gaining Trust R&D Approval

NHCT Research Management and Governance Department are committed to making research easier, faster and more accessible. During 2012/2013 NHCT has issued 8 Honorary Research Contracts and 50 Letters of Access to researchers undertaking projects within Nottinghamshire County CCGs.

Over the past 12 months, there have been 41 projects which have been approved by the organisation of which 36 are NIHR-adopted and 5 are Non Portfolio (staff, student or other Non-Portfolio studies). The current turnaround for research approval for Non Portfolio studies within NHS Nottinghamshire County CCGs, on receipt of a complete valid application, now averages **7** days. For NIHR-adopted studies, the turnaround time for approval is **12** days. The time taken for the review and approval processes is dependent upon the type, complexity and resource needs of each study.

This report offers an overview of NHS Nottinghamshire County CCGs research achievements and activity for the 2012/2013 period. The first section of the report focuses exclusively on the research activity that has taken place within NHS Nottinghamshire County CCGs. The second section of this report looks more closely at the Key Performance Indictors used to measure the performance and research activity within NHS Nottinghamshire City CCGs.

3. NHS Nottinghamshire County CCGs Research Delivery 2012/2013

3.1. Recruitment to NIHR adopted Studies

During 2012/2013, NHCT recruited 525 participants to 36 NIHR-adopted studies. This figure represents recruitment to commercial and non-commercial studies, which have been adopted onto the NIHR portfolio. Figure 1 represents the proportion of patients recruited into NIHR-adopted and non-portfolio studies by directorate during 2012/2013.

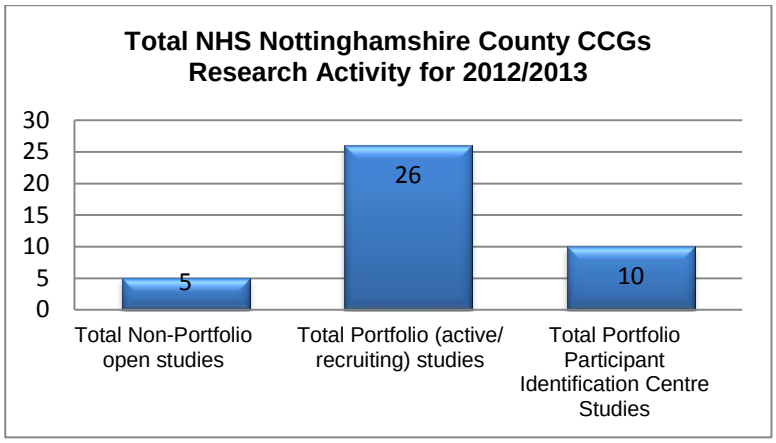
3.2 Total Research Activity for NHS Nottinghamshire County CCGs

The number of active NIHR portfolio studies and Non-Portfolio studies recruiting within NHS Nottinghamshire County CCGs gives an indication of the efficiency and success of research activity taking place. During 2012/2013 NHS Nottinghamshire County CCG participated in 41 studies, of which 36 were NIHR adopted and 5 of which were non-portfolio studies (Figures 1 and 2).

Figure 1: Total Studies NHS Nottinghamshire County CCGs 2012/2013

	2012/2013
Total Non-Portfolio open studies	5
Total Portfolio (active/ recruiting) studies	26
Total Portfolio Participant Identification Centre Studies	10
Total Portfolio Open Studies	36

Figure 2: Bar Chart Highlighting Total NHS Nottinghamshire County CCGs Research Activity for 2012/2013



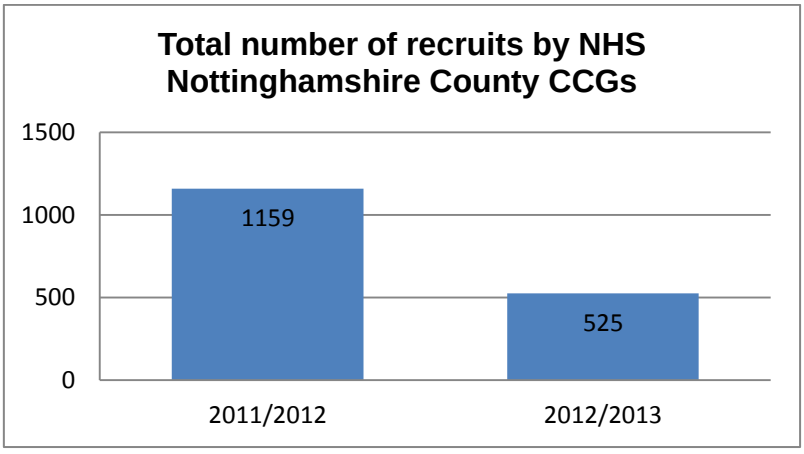
3.3 Total Patient Recruitment for NHS Nottinghamshire County CCGs

The number of patients recruited into studies is a useful high level indicator of the overall size of the Trust's research portfolio. These KPI's are routinely used in local and national comparisons between organisations. Figure 3 and 4 demonstrate the total number of recruits by NHS Nottinghamshire County CCGs for both 2011/2012 and 2012/2013. There has been a decline in recruitment to NIHR Portfolio studies since 2011/2012.

Figure 3: Total Number of Recruits to NHS Nottinghamshire County CCGs 2011/2012 and 2012/2013

	2011/2012	2012/2013
Total number of recruits by NHCT	1159	525
Total PIC Activity	N/A	N/A

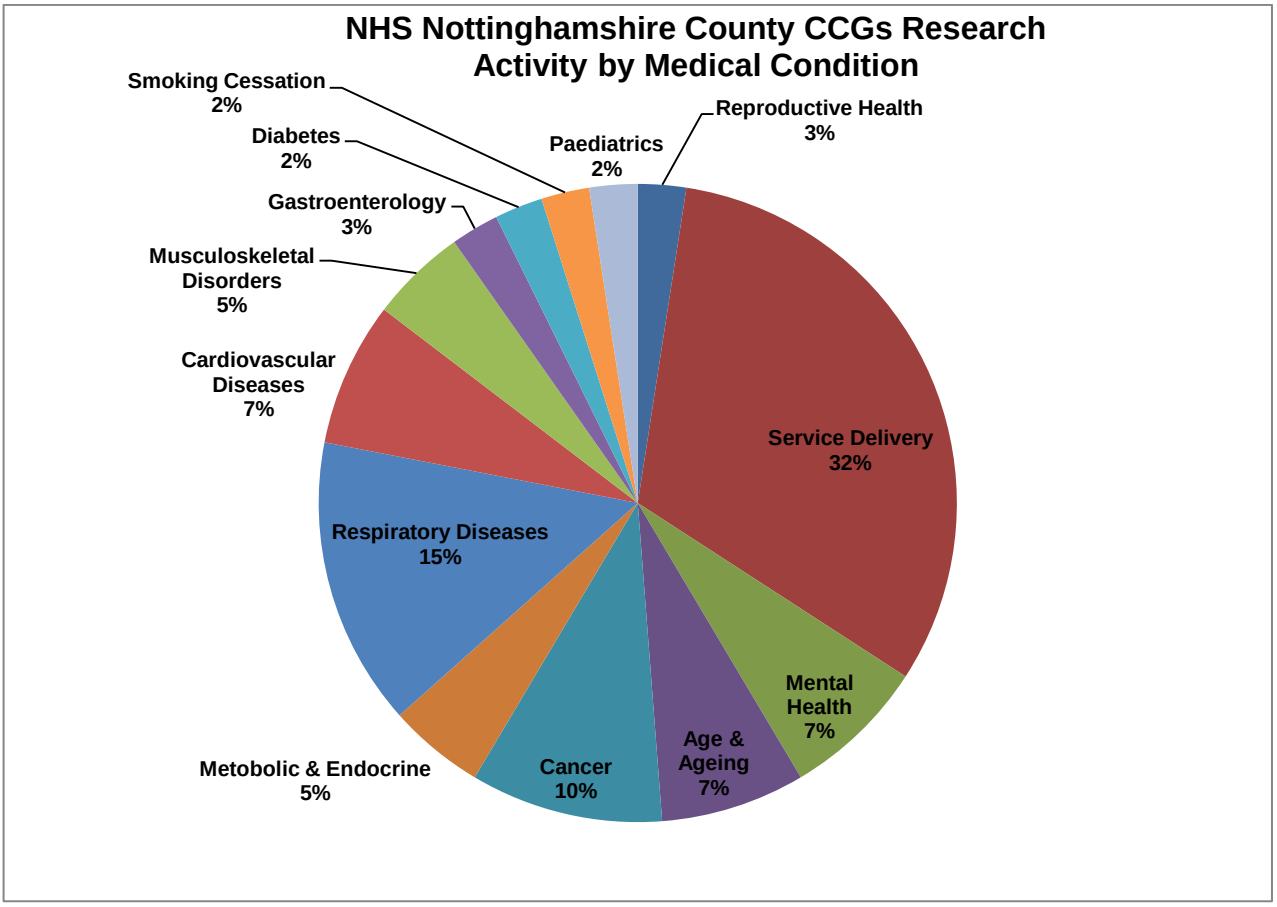
Figure 4: Barchart Comparison of Total Number of Recruits to NHS Nottinghamshire County CCGs 2011/2013 and 2012/2013



3.4 Breakdown of NHS Nottinghamshire County CCGs Research Activity by Medical Condition 2012/2013

NHCT records the number of studies for each medical condition. This enables the Trust to monitor over-researched medical conditions within NHS Nottinghamshire County CCGs and to ensure that there is an equal distribution of research being conducted over a variety of disease areas. Figure 5 highlights the total number of studies for each medical condition within NHS Nottinghamshire County CCGs for 2012/2013.

Figure 5: Research Activity for NHS Nottinghamshire County CCGs by Medical Condition 2012/2013



Research exploring service delivery (32%) is the most prevalent topic to be explored within NHS Nottinghamshire County CCGs for both Portfolio and non-portfolio studies. This is followed closely by research exploring Respiratory Diseases (15%), and Cancer (10%). The most underresearched areas include Paediatrics (2%), Diabetes (2%), Smoking Cessation (2%), Reproductive Health (3%) and Gastroenterology (3%).

4. NIHR Key Performance Indicators

4.1. Overview

> *"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 research"* (NIHR, *Contract Performance FAQs,* 2012)

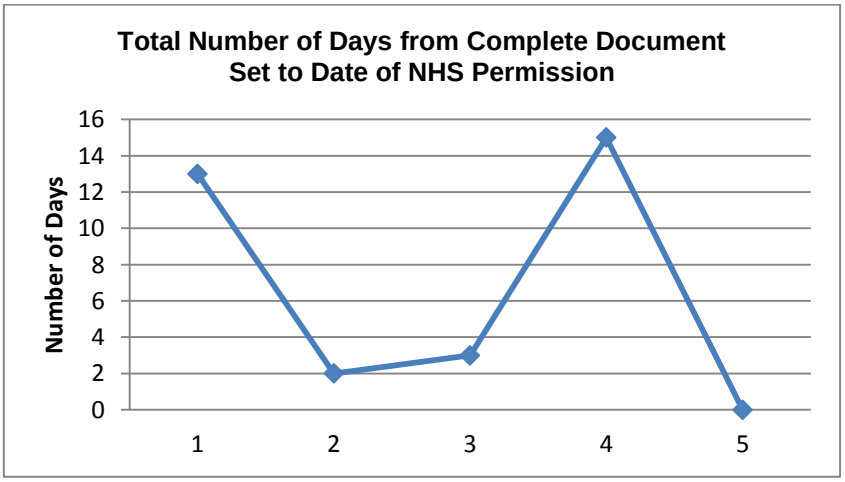
Within this section, the NIHR key performance indicators will be explored. This KPI's include both the turnaround times for research happening within NHS Nottinghamshire City CCGs.

4.2 Median time (calendar days) from date local site Complete Document Set Validated to Date of NHS Permission

There is a national target of 30 days from receipt of a Local Site Complete Document Set Validated to date of study receiving NHS Permission. This target is designed to get NIHR Portfolio studies set up and recruiting patients as quickly as possible.

During 2012/2013 the average turnaround time from the date Local Complete Document Set was validated to the Date of NHS permission was **12** days. Figure 6 highlights the total number of days taken from the date in which the complete local document set was validated to date of NHS permission 2012/2013

Figure 6: Line Graph Demonstrating turnaround time from Complete Document Set Validated to Date of NHS Permission 2012/2013

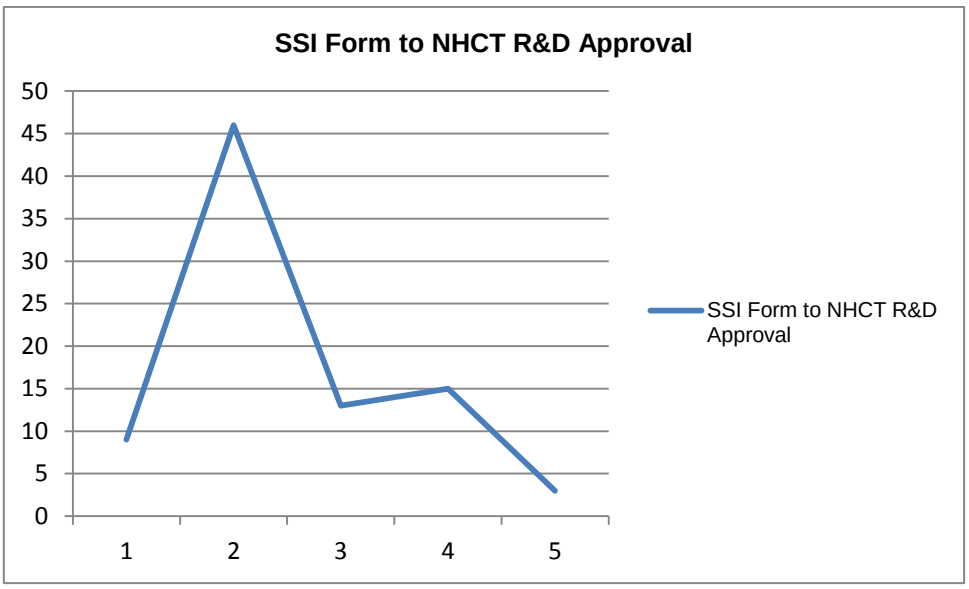


4.3 Median time from Site Specific Information Form submission to NHCT R&D Approval (Trust R&D Route)

There is a national target of 30 days for R&D approval being given to a study, which is measured from receipt of a valid application for R&D approval to R&D approval being granted. This target is designed to get studies set up and recruiting patients as quickly as possible and also gives an indication of efficiency of the governance and setup process at NHCT.

During 2012/2013 the average turnaround time from the date the SSI form was submitted to the date of the study gaining Trust R&D approval was **40** days. Figure 7 highlights the total number of days taken from the date the SSI form was submitted to date of R&D approval.

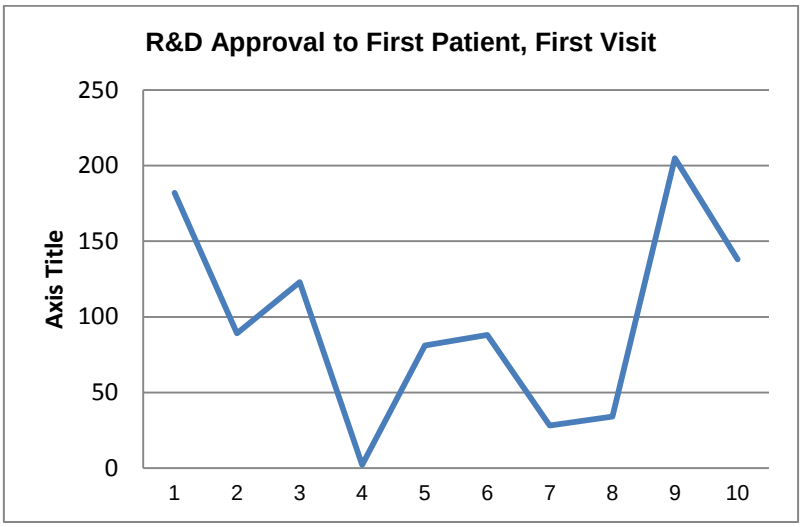
Figure 7: Line Graph Demonstrating turnaround time from date SSI Form was submitted to date R&D Approval was obtained 2012/2013



4.4 Median time from R&D Approval to First Patient, First Visit

There is a national target of 70 days for recruitment of the first patient to a research study. The 70 day benchmark is measured from receipt of a valid application for R&D approval, to the first patient being recruited into the study. The target is designed to get research studies set up and recruiting patients as quickly as possible and also gives an indication of efficiency of the governance and setup process at NHCT. The average number of calendar days taken from date the study received NHCT R&D approval to the date the first patient was recruited during 2012/2013 is **97** days.

Figure 8: Line Graph Demonstrating turnaround time from date R&D Approval was given to date the First Patient was recruited 2012/2013



Please not that although 97 days is the average turnaround time from the date R&D Approval was given to the date the first participant was recruited, this is not an accurate reflection of the performance of NHS Nottinghamshire County CCGs as data was not recorded on many of the study files. NHCT Research Management and Governance Department endeavor to ensure that data is uploaded to the Portfolio to ensure that there are no discrepancies with the data produced for such KPI Reports.

5. Key Terms

Glossary of Key Terms	
NIHR	The National Institute for Health Research (funded through the Department of Health) is a large, multi-faceted and nationally distributed organisation created to "maintain a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public" (NIHR, 2010).
Trent CLRN	Trent CLRN is one of 25 Comprehensive Local Research Networks (CLRNs) as part of a national research network infrastructure.
Portfolio	Refers to studies adopted by the NIHR. The funders of Portfolio studies are predominantly NIHR itself, as well as major medical research charities and Research Councils. Studies that are funded through major funders, via peer reviewed open national competition are eligible for inclusion on the NIHR Portfolio, as well as on a case by case basis. CLRN funding is provided to support NIHR Portfolio adopted studies. Some Commercial research is also adopted but no funding is provided from the CLRNs.
Non-Portfolio	These studies are not eligible for adoption by the NIHR Clinical Research Network (CRN) Portfolio and are not sponsored by an industry company. These studies include those undertaken for education purposes (student led) and those that are funded through the researcher's own accounts, or departments
Commercial Studies	Commercial studies refer to research that is funded and sponsored (i.e. contracted) by commercial companies, such as pharmaceutical companies and medical device companies.
Non-Commercial Studies	Non-Commercial studies refer to all other research. Such studies are funded by non-commercial organisations such as the NIHR, a research council, major medical research charities or other local funding. Studies funded by a grant from a commercial company, but sponsored by a non-commercial organisation are also referred to as non-commercial.
R & D Approval	R&D approval provides permission for studies to commence within Nottinghamshire Healthcare NHs Trust and is required for all research studies involving NHS patients, their tissues/ information, and studies involving NHS staff participating by virtue of their profession. R&D approval ensures that legal obligations of the board, outlined in the *Research Governance Framework* (2nd Edition, 2006) are met and is a condition of ethical favourable opinion. NHS permissions are issued following on from a formal review of the project by designated staff.
PIC Studies	Participant Identification Centres (PIC) are responsible for the identification of potential participants who are subsequently invited to take part in research through a different site which takes on responsibility for seeking consent and undertaking research procedures. The PIC retains responsibility for the healthcare of the patient outside the research, but the research site takes on the duty of care for them in relation to the research study.