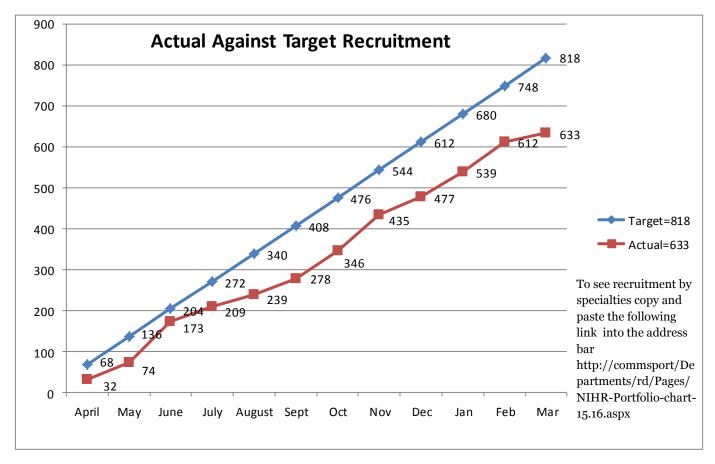
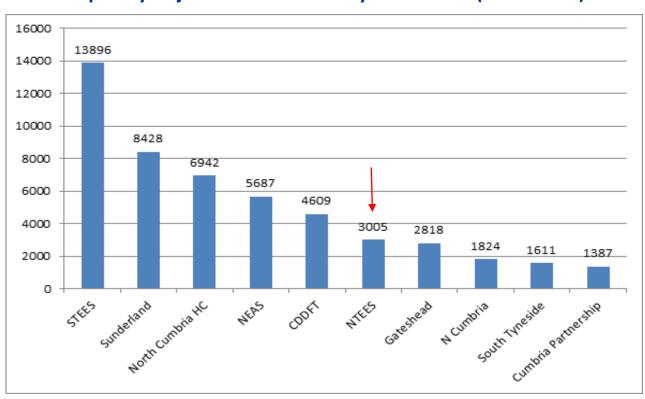


R&D MARCH NEWSLETTER

RECRUITMENT 2016/17 - ODP DATA CUT DATE 03/04/2017



Complexity Adjusted recruitment by acute Trust (excl. NUTH)



At the time of writing we have recruited **633** patients against our target of **818** (77%). I anticipate we will close the year with around **700** patients (86%). This is the first year we haven't achieved our recruitment target but have been faced with some external factors beyond our control.

National HRA processes have impacted on the availability of studies for recruitment within anticipated timescales and some specialties have seen a national decline in the number of studies available (GI and Respiratory). It should be noted that we have continued to increase the number of commercially sponsored studies open overall and continue to be approached as a recruiting site based on our past performance (Cardiology, Respiratory and GI). We have also seen our Stroke, Cancer and A&E teams increase their activity along with many studies open or planned within new areas (Anaesthetics and Critical Care).

Our **Obs & Gynae** and **Neonatal** research teams are a fantastic examples of how activity can increase dramatically when all of the clinical team is engaged with research—their only limiting factor now is the availability of research midwives to support their enthusiasm for studies they are approached about!

In some areas we struggle as the majority of available studies are either designed for primary care recruitment (**Diabetes**) or we have a limited service at our Trust (**Dermatology**), however even in these areas a lot of work has been done to embed research into their processes and recruit where we can. **Orthopaedic** and MSK studies are increasing with the support of some funding into the department and surgical nurse time. It's hoped that our 12 month programme to support the **Out of Hospital Directorate** to open studies will see an impact on recruitment in **Jane Greenaway**

FROST (Frozen Shoulder Trial)

Congratulations to Mr Rajesh Nanda and the orthopaedics staff for being the second highest recruiters to the FROST Trial in February. They were also the first UK site to provide tissue and blood samples for the sub-study. Well done!

TOP 5 RECRUITING STUDIES FOR MARCH

1. DETECT 1 Study
Cancer team 6

ANODE study
Reproductive Health and 6
Child Birth team

2. Respiratory team

3. QUIDS Study
Obs & Gynae team

IMPRESS study 1
 Cancer team

1

5. EMPRESS study

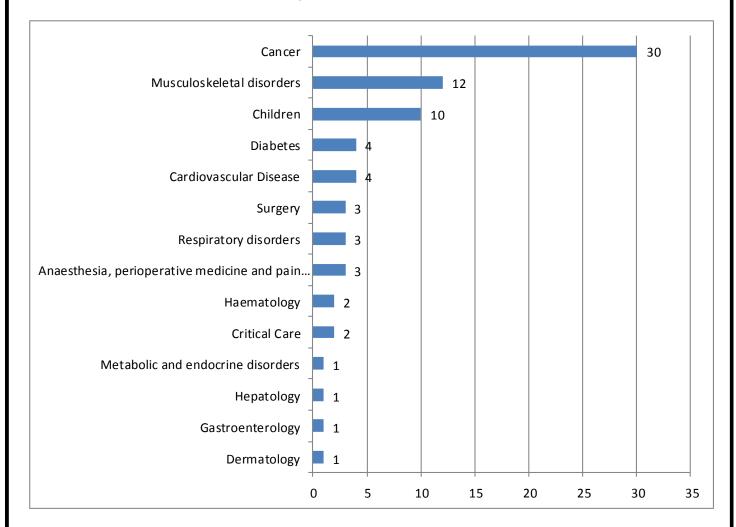
Cancer team

WASH Study—GI

Congratulations to Prof Matt Rutter—his "Water Assisted Colonoscopy Study" has been successfully awarded funding from the NIHR RfPB Funding scheme. This is a multicentre study which will run across 5 sites from Autumn 2017. It's a collaboration between ourselves and the CTU in Bangor along with local GI colleagues.



Expressions of Interest (EOI) for commercial studies Frequency of "No response to EOI"



OPEN COMMERCIAL STUDIES: ODP DATA CUT 24/03/17.

| Specialism | Principal Investigator | Study name | Total Target recruitment | Total Actual Recruitment |
|-----------------|---------------------------|---------------|--------------------------|-----------------------------|
| Recently opened | studies | - | | |
| Cardiology | Dr Justin Carter | RELAX EU | 1 | 0 |
| Stroke | Dr I Anwar | PGRX | 5 | 1 |
| Cardiology | Dr Justin Carter | DALGENE | 8 | 0 |
| Cancer | Dr Darren Leaning | Titan | 3 | 0 |
| Obs&Gynae | Dr Iona McLeod | Premium | 10 | 2 |
| | • | • | | |

Cancer Team Trials:

The North Tees Cancer Trials Team consented their first patient to the **TITAN study** on 28th Feb 2017. This is a double blind placebo controlled trial for metastatic prostate cancer, which is the first commercial trial for the Urology department at North Tees.

The Cancer Trials Team have also consented their first patient for the **MUK 8 study**. This trial randomises relapsed multiple myeloma patients to receive the new drug Ixazomib in combination with dexamethasone and cyclophosphamide or dexamethasone and cyclophosphamide alone. Congratulations from sponsor was published in the recent MUK 8 newsletter.

The colorectal trial **IMPRESS** now also has it's first patient, recruited on the 20th March 2017. This trial randomises sigmoid cancer patients to receive a pre-operative MRI or not. This trial has been challenging to recruit to without prolonging the patients pathway before treatment. Giving a presentation at the endoscopy users meeting has been greatly helpful and led to our first recruit thanks to Dr Wells.

DISSEMINATION OF RESULTS UKFOCCS—Cancer Trial

A study supported by the NIHR CRN has published its results in the Journal of Clinical Oncology. The study was open at North Tees and Hartlepool and recruited 17 patients.

The UK Familial Ovarian Cancer Screening Study (UKFOCSS) is a national multi-centre study in which 4,348 women with a one in ten or greater risk of developing ovarian cancer due to family history, faulty gene, took part in after declining surgery. For women at high risk, the current medical advice is to have their ovaries and fallopian tubes removed after having completed their families, but many women delay or decide against having the surgery.

The UKFOCSS results indicate that four monthly screening with the Risk of Ovarian Cancer Algorithm (ROCA) may be an option for these women until they decide to undergo surgery. The algorithm is used to look for rising levels of a blood protein, CA 125, which can be elevated in ovarian cancer. Over the three years of screening and in the year after the last test, nineteen women were diagnosed with ovarian cancer although none had any symptoms. The screening was estimated to be able to pick up 9 out of every 10 cancers. A further 18 women were diagnosed with ovarian cancer in the five-year period that followed. Seventeen (94%) of these 18 women had advanced stage cancer (IIIB-IV) compared to seven (37%) of the 19 diagnosed during the screening phase.

http://www.nihr.ac.uk/news/ovarian-cancer-study-could-lead-to-screening-for-high-risk-women/5662

EXCELLENCE IN STUDENT NURSE PLACEMENTS

R&D Research Delivery Staff at North Tees have been awarded an Excellence Certificate for student nurse placements as part of the service improvement placements in October 2016 from Teesside University, School of Health & Social Care. Working with R&D Administrator Pauline Shepherd.

GOOD NEWS - TRUST BASED GCP TRAINING

We will be providing a Trust Based "Introduction to GCP Training" session

Tuesday 26th September, Lecture Theatre, Middlefield Centre, 9am – 4pm

Please make sure you disseminate this widely so that we can ensure the course ids fully booked. I've been fighting for this for 4 years from the network so we need to demonstrate that it is needed and is therefore fully booked. Would be ideal for new junior doctors on rotation so that they can be added to delegation logs and assist with recruitment – all good CV stuff!

Other local GCP Training: GCP Refresher

This course is for experienced research delivery staff who have previously completed GCP training and it runs for 3 hours.

The dates and local venues are:

Wednesday 05/04/2017 09:30-12:30 Riverside Stadium, Middlesbrough

Wednesday 24/05/2017 09:30-12:30 Morrison Trust, Darlington

To book a place on CRN North East and North Cumbria training (class based and e-learning), please copy and paste this address in to your web browser https://learn.nihr.ac.uk/

Synexus Update

Work is underway on the ground Floor of the Middlefield Centre, walls are now down and being re-built with the expectation that the research facility will be operational in June. There will be an official opening of the Facility at the Joint **R&D**: Synexus Conference on Wednesday 13th September where the keynote speech will be given by Prof Jonathan Sheffield, NIHR Chief Executive. Due to the limited capacity of the lecture theatre this will unfortunately be an "invite-only" event with invitations being sent in April.

Staffing Update

We say a very sad farewell to several members of staff in the next few months.

Sue Kelsey, Cross specialty research nurse (Diabetes/ Dermatology) will be leaving us. Sue has worked tirelessly for

research since 2010 and will be a huge loss to the R&D department, however we wish her well in her new post as Diabetes Specialist Nurse and hope that she will still be able to assist with identification of potential patients!!

Sara Essex, Cancer Trials Co-ordinator leaves us for a promotion to Cancer Trials Practitioner at James Cook. Sarah has been with us since 2015 and quickly established herself as indispensible in the cancer team with an immediate impact on recruitment. We wish her luck in her new role over the river.

Deborah Smith, Data Assistant (GI and Hepatology). Debbie has been with the department since 2012 providing vital data support for GI and Hepatology and occasionally R&D. Debbie is moving onto pastures new and we wish her the very best of luck in her new ventures.





North Tees and Hartlepool
NHS Foundation Trust

Clinical Research Network North East and North Cumbria

| | Research Staff | |
|----------------|--|-----------------------|
| Director | Professor Samir Gupta | 24090 |
| Manager | Jane Greenaway | 83251 |
| Team leader | Lynne Williams | 83253 |
| Facilitator | Shaz Khalid | 24733 |
| Administrator | Pauline Shepherd | 24090 |
| Data Assistant | Jean Bage | 83046 |
| Cardiology | Julie Quigley & Pam Race | 83114 |
| Paediatrics | Heather Walker, Carolyn Campbell & Rebecca Tate | 46041 |
| Neonates | Alex Ramshaw & Rebecca Tate | 24247/24248 |
| Respiratory | Nicola Bateman, & Claire Irish | 24580/24581/245 82 |
| Obs & Gynae | Sharon Gowans, Alison Samuels, Rebecca Tate | 83111 |
| A&E | Laura O'Rourke | 83204 |
| Diabetes | Sue Kelsey | 83116 |
| Dermatology | Sue Kelsey | 83116 |
| Stroke | Susan Crawford | 83706 |
| Cancer | Helen Wilson , Sarah Essex, Alison Chilvers | 83277 |
| GI /Hepatology | Carol Adams, Deborah Wilson, Anne Eastick, Lynda Poole, Deborah Smith | 24164/24524 |
| Surgery | Debbie Wilson, Liz Baker | 24163/83778 |

If you have any good news research stories to share with us we would love to feature them in our next newsletter so please email Jean and tell us what you have been up to... Jean Bage: 01642 383046 jean.bage2@nth.nhs.uk

For more information (internal) please use link below:

Research and Development, Middlefield Centre, North Tees and Hartlepool NHS Foundation Trust, Hardwick Road, Stockton-On-Tees TS19 8PE.