



Gateshead Health
NHS Foundation Trust

Research and Development (R&D) Annual Report April 2018 – March 2019

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EXECUTIVE SUMMARY

In the 12 months from 1st April 2018 to 31st March 2019, Gateshead Health NHS Foundation Trust recruited 1,241 patients across 54 National Institute for Health Research (NIHR) portfolio studies. The Research & Development Department are aligned to the Trust Vision, Values (ICORE - Innovation, Care, Openness, Respect and Engagement) and Goals. The Department also links to the Strategic Trust Priorities, specifically around working with partners, managing and improving the health of the population of Gateshead, promoting wellbeing and preventing the occurrence and progression of ill-health wherever possible; whilst ensuring all of the services we deliver will be good or outstanding as well as being safe, effective, caring, responsive and well-led.

The Research & Development (R&D) Department have seen many successes over the last 12 months:

- Quality Improvement Incentive Scheme – Data Completeness for Recruitment Activity within the Local Portfolio Management System (LPMS) achieved during Quarter 4
- Research activity increased in priority areas – Hepatology, Respiratory and Surgery
- Bank Research Nurse Initiative – continued success with additional studies being opened
- CQC Inspection – ensure Trust readiness, as research is now incorporated in the Well-Led Framework
- Continued success as a contributing Partner Organisation within the North East & North Cumbria Local Clinical Research Network
- Trust Open Day – the R&D Department were invited to attend to showcase research within the Trust

The Trust continues to demonstrate its commitment to improving the quality of care it offers and making its contribution to wider health improvement. In line with North East and North Cumbria: Clinical Research Network, the Trust has focused on building the recruitment for both Portfolio and Industry studies.

1. INTRODUCTION

The Government's revised mandate to NHS England for 2018/19 was to support research, innovation and growth and to support the Government's implementation of EU Exit in regards to health and care. (Objective 7):-

"Just as a strong NHS depends on a strong economy, so a strong NHS can contribute to the growth of a strong economy, especially in health and life sciences. We ask NHS England to promote and support participation by NHS organisations, patients and carers in research funded both by commercial and non-commercial organisations, so that the NHS supports and harnesses the best research and innovations and becomes the research partner of choice. We expect to see NHS England help the NHS contribute to economic growth, to support the NHS to reduce the impact of ill health and disability, and to support and harness research and innovation to enable cost effective, affordable, transformative new treatments

to reach patients and their carers more quickly, whilst also securing better value from companies. As part of this, we expect NHS England to work with the life sciences sector and Government as it takes forward a life sciences strategy that makes the UK the best place in the world to invest in life sciences and develop innovative, cost effective and affordable new products”.

NHS Research Plan 2018/19

Our Mandate commitment	•The Department of Health requires us to promote and support participation by NHS organisations, patients and carers in research funded both by commercial and noncommercial organisations, so that the NHS supports and harnesses the best research and innovations and becomes the research partner of choice.
Five Year Forward View	•We will improve the NHS’ ability to undertake research and apply innovation •Research is vital in providing the evidence we need to transform services and improve outcomes e.g. in developing new care models, redesigning urgent and emergency care, strengthening general practice and transforming mental health and cancer services.
Business Plan	•By using evidence to help shape services for patients, we can tackle variations in care, help identify the causes of disease, improve the treatment of patients, increase organisational efficiency, and help attract inward investment to the UK. •We will deliver the NHS contribution the 100,000 Genomes project.

The Next Steps on the NHS Five Year Forward View (March 2017) states “As medicine transforms over the next 20 years, the cutting-edge technology in our Universities combined with the NHS presents unique conditions to create new industries, companies and jobs based in the UK and transform the way innovation is delivered to patients, offering an attractive place to research and test new treatments in partnership with innovators. Potential areas include artificial intelligence, the application of genomics to medicine, the development of a range of new diagnostic tools, and therapies for conditions that will enable more healthy aging”.

Gateshead Health NHS Foundation Trust has remained a research active organisation following the NHS Research Plan to ensure that our patients have access to the very latest treatments and technologies and by contributing to the 100,000 Genomes Project.

This report highlights a number of key achievements, the Trusts expanding research portfolio and performance against national performance metrics and high level objectives during 2018/19.

2. NATIONAL AND LOCAL CONTEXT

The NIHR is the clinical research arm of the NHS and the nation's largest funder of health and social care research which provides people, facilities and technology that enables research to thrive.

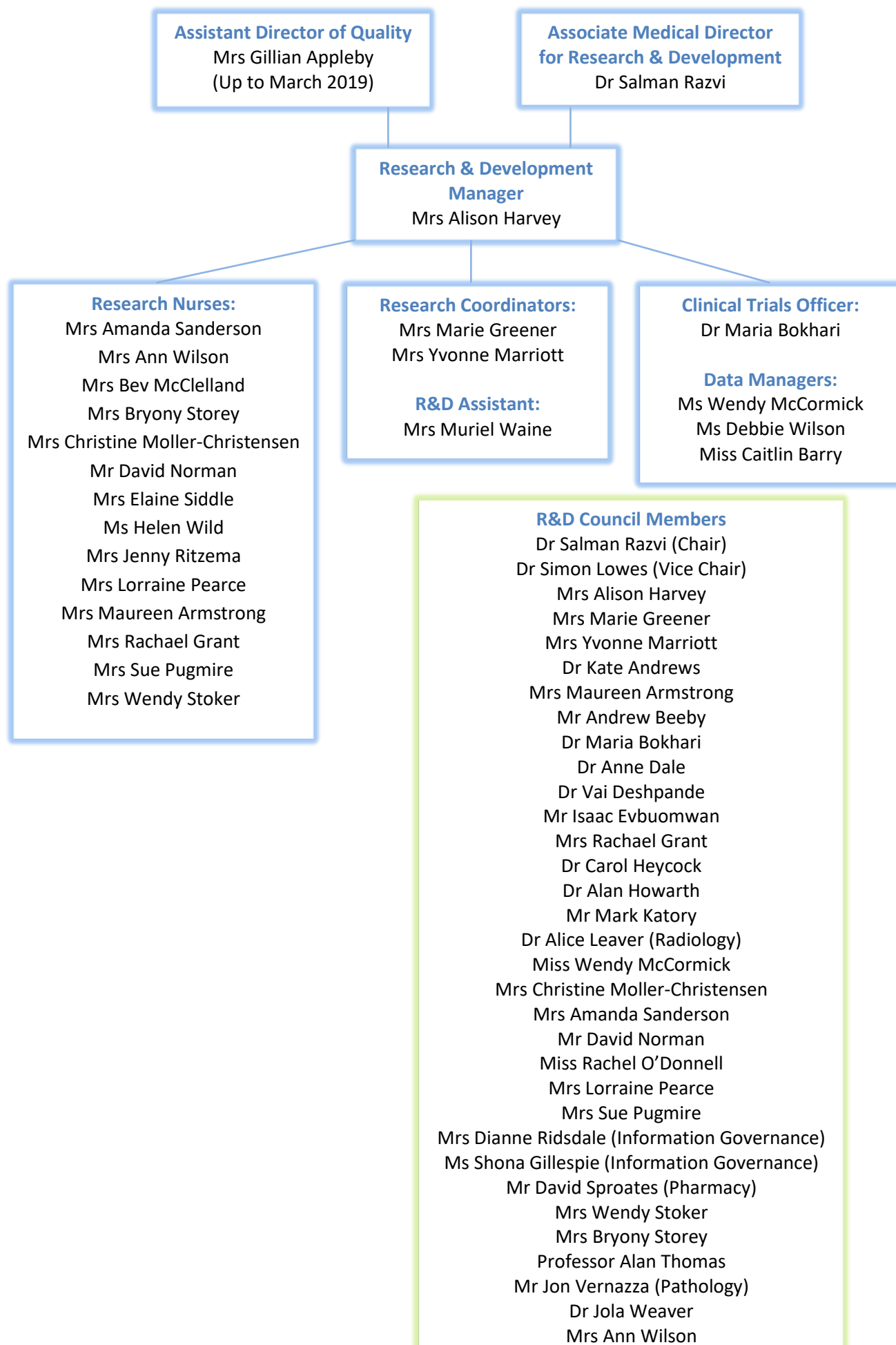
The NIHR funds fifteen Clinical Research Networks across England and their mission is to improve the health and wealth of the nation through research. Their mission delivers through five strategic work streams:-



Gateshead Health NHS Foundation Trust is a Partner Organisation of the Clinical Research Network: North East and North Cumbria (CRN NENC).

The Trust has a long and successful relationship with the network delivering a number of NIHR Portfolio studies across a range of specialties.

3. RESEARCH AND DEVELOPMENT TEAM



4. Gateshead Work Experience Project

Work experience placements are essential to young adults who would like to experience the world of work and gain information about a range of careers in order to make informed career choices.

Providing work experience placements enables the Trust to build invaluable links with the surrounding community through working with local educational establishments.

In 2018 the R&D Department offered a work experience placement to a student from Lord Lawson of Beamish Academy, Birtley.

During the student's placement they learnt how important research is and they were able to shadow members of the Research Team, visit clinics and meet research patients. They also learnt resuscitation and had a tour of Pathology and spent a day with the SafeCare Team.

5. NON-EXECUTIVE DIRECTOR FOR RESEARCH

Mr David Shilton is a Non-Executive Director for the Trust and part of his portfolio includes Research & Development. David meets with the R&D Manager on a regular basis to discuss Network/Research issues and attends the R&D Council Meetings when possible. David is an active member of the Non-Executive Director Research Champions Meeting held by the NE & NC CRN at their Headquarters in Regent Point, Gosforth.

6. RESEARCH AND DEVELOPMENT COUNCIL

The R&D Council is Chaired by Dr Salman Razvi (Associate Medical Director for R&D) and is responsible for supporting research delivery and research training, ensuring appropriate levels of recruitment to NIHR Portfolio studies, ensuring the Trust complies with the UK Policy Framework for Health & Social Research and Good Clinical Practice. The R&D Council also approves Standard Operating Procedures and Policies relevant to Research and Development.

The R&D Council assesses the Trust's capacity and capability to take part in proposed research projects using Trust facilities, patients and staff.

The R&D Council holds two meetings each month - R&D Council (full Council Meeting) and an Interim R&D Council Meeting (for study assessment only). The Interim Council Meeting is currently chaired by Dr Simon Lowes (Vice Chair).

There are 33 Council Members - Consultants, Research Nurses, R&D Staff and Support Service Staff (Pathology, Radiology, Pharmacy, & Information Governance) who either have an active role in research or an interest in research.

7. RESEARCH ACTIVITY

R&D assessed 28 new NIHR portfolio studies in 2018/19 for capacity and capability and recruited to 54 portfolio studies across 19 clinical specialties. In total, 1,241 patients were recruited. This was a decrease of 73 patients.

28 Expressions of Interest were submitted for studies that the Trust would like to participate in.

Recruitment by clinical specialty and study is outlined in Table 1. (below):-

TABLE 1: 2018/19 RECRUITMENT BY SPECIALTY & STUDY

All recruitment figures are taken from the NIHR Open Data Platform (ODP).

Clinical Specialty	Study Title	Recruits in 18/19
Anaesthesia	PQIP	88
	DALES	142
Cancer	MAMMO-50	27
	HORIZONS	23
	Add-Aspirin	11
	OPTIMA	9
	FLAIR	1
	ESTHER	1
	SMP2	13
	Newday ABC	6
Cardiology	The BHF SENIOR-RITA Trial	3
Critical Care	PEPTIC	132
Dementias and Neurodegeneration	Skin Metabolites in Parkinson's Disease	16
	SUPERB	3
	What can gait analysis tell us about dementia and its subtypes	1
	Parkinson's Pen Project	18
	SYMBAD	16
	The Angela Project	5
	AD Genetics	3
Diabetes	ADDRESS 2	1
	OPTION DM	1
	Trial Net	1

Clinical Specialty	Study Title	Recruits in 18/19
Gastro	ContactME-IBS	23
	OVERLAP (<i>Recruitment recorded under Rheumatology</i>)	49
	IBD Bioresource	56
	PREdiCCt	1
Gynaecological Oncology	ROCKeTS	13
	MROC	4
	100,000 Genomes	6
Health Services and Delivery Research	HISLAC	65
Hepatology	UK PBC Genetics Study	4
	UK PBC Nested	0
	UK-AIH	0
Injuries & Emergency	GPs in ED	13
	ACJ Injuries	4
Metabolic and Endocrine	SANOFI DUS	2
	PETS	29
Mental Health	EPICC-ID	2
Paediatrics	Genetics of Obesity Study (GOOS)	12
Reproductive Health & Childbirth	ANODE	10
	QUIDS	29
	Endometrial Scratch	14
	QUIDS-2	12
	PREP (MS-E-CIG)	137
	STOPPIT-2	2
Respiratory	EME TIPAC	1
Rheumatology	The GCA Study	162
	TITRATE	3
	BRAGGSS Study	1
	UKIVAS	1
	OVERLAP	3
	WORKPROMS	10
	DyNAMISM	6
	BIOFLARE	4
	BSRBR	1
	PreventRA	1
Stroke	ACTIVATE	4
Surgery	KReBS	42

8. RESEARCH ACTIVITY BY SPECIALTY

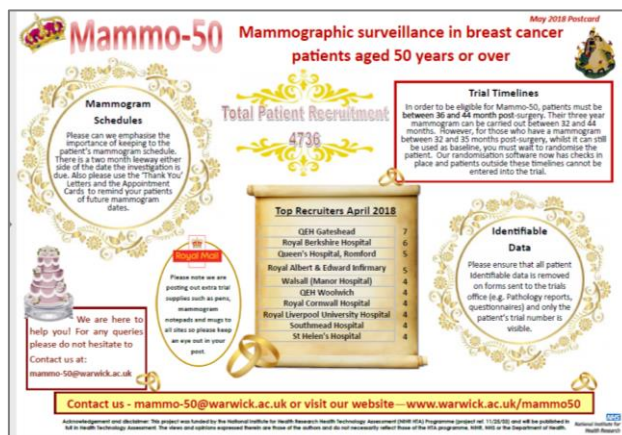
Research at Gateshead is active in multiple clinical specialties. Highlights from several of these areas are presented below.

Cancer

The Cancer Team have had another successful year, recruiting a total of 91 participants across 8 studies and were the fifth highest recruiting Research Team within the Trust for 2018/2019.

The Trust's MAMMO-50 Research Team - Dr Sally Athey (Principal Investigator), Dr Maria Bokhari (Clinical Trials Officer), David Norman (Research Nurse) and Caitlin Barry (Data Manager) were the highest recruiting team in April 2018. They received a 'Royal Wedding' themed postcard highlighting their achievement.

Later in the year (October 2018) they were awarded another certificate after recruiting their 100th patient.



Cardiology

The Cardiology Team (Principal Investigator - Dr Ray Meleady), Bev McClelland (Research Nurse) and Wendy McCormick (Data Manager) only have 1 active study at the moment, the British Heart Foundation, Senior Rita Trial. Recruitment hasn't been easy for the Team as potential participants for the study need to be aged 75 and over and tend to be very frail. They have currently recruited 3 participants.

Critical Care/Anaesthesia

The Critical Care / Anaesthesia Research Team (Research Nurses Jenny Ritzema and Amanda Mulholland) were our top recruiting Research Team in 2018/2019 recruiting a prodigious 362 participants over 3 studies.

The PEPTIC study (Principal Investigator - Dr Vanessa Linnett) is investigating two different types of medicine which help to prevent stress ulcers for intubated patients has recruited 132 participants.

The PQIP Study (Principal Investigator - Dr Andy Bracewell) is looking at what happens to patients before, during and after major surgery on their bowel to see if improvements can be made, has recruited 88 participants.

New to research this year was Dr Catherine Bartley who took on the role of Principal Investigator for the Dales study - a snap shot study which concentrated on patients coming into hospital for planned surgery, who had common allergies and were wearing a red wristband, to try and find out what effect the allergies might have on the patient during their stay. In just 3 consecutive days they were able to recruit 142 participants.

Dementias & Neurodegeneration

Over the past year, Bryony Storey and Elaine Siddle (Research Nurses) have recruited 62 participants across 7 studies. The main studies investigate both dementias and Parkinson's disease:-

The Parkinson's Pen Project (Principal Investigator - Dr Richard Athey) is using a new "pen like" device to see if it can help diagnose Parkinson's disease more accurately.

Skin Metabolites in Parkinson's Disease (Principal Investigator - Dr Richard Athey) involves a skin swab being taken to see if it can help diagnose Parkinson's disease earlier.

SYMBAD (Principal Investigator - Professor Alan Thomas) is a drug trial for people who have Alzheimer's Disease or Alzheimer's and Vascular Dementia (combined) who experience agitation.

The ANGELA Project (Principal Investigator - Professor Alan Thomas) is a questionnaire study for younger people living with dementia who received their diagnosis before their 65th birthday. The participants and their families, friends or Carers can get involved in the study which hopes to find out what it is like to live with dementia at a younger age and what support would make life better for younger people with dementia and their families.

New NICE guidelines in June 2018 recommended that everyone should be told about dementia research opportunities, as currently there is an estimated figure of 850,000 people in the UK living with dementia. The only way to find new and better ways to treat and care for those affected by the condition, is to do more research.



The Trust actively encourages people to register their interest in the Join Dementia Research campaign <https://www.joindementiaresearch.nihr.ac.uk>

In December 2018 The Dementias & Neurodegenerative Diseases Research Network (DeNDRoN) Steering Group congratulated and thanked everyone in the Region for their important contribution and support for the DeNDRoN portfolio during 2018.

Nationally DeNDRoN finished the year as the top recruiting network – which is a fantastic achievement and reflected everyone’s hard work and commitment. Their outstanding recruitment performance was also commended by the DeNDRoN LCRN Executive.

Dr Daniel Collerton, Consultant Clinical Psychologist and Head of Clinical Psychology Services for Older People in Gateshead and active researcher, retired from the Trust on 1st October 2018.

Gynaecological Oncology

In 2018/2019, the Gynaecological Oncology Team recruited 23 participants across 3 studies.

The MROC Study (Principal Investigator - Miss Chris Ang) is looking at recent developments in MRI imaging which have led to a new MRI technique called multiparametric MRI (mpMRI), which has the potential to provide additional information that may influence decisions about how ovarian cancer patient should be treated.

Current guidelines recommend that a CT scan is performed in order to inform decisions as to what stage the cancer is at, and if the patient should have upfront surgery.

The MROC study began set up in 2016, but due to many setbacks, the study wasn’t able to actually open at Gateshead until August 2018. It was therefore fantastic news to receive the November 2018 Newsletter and read that Gateshead, along with Liverpool and Gloucestershire, were the highest recruiters at that point.

**Huge congratulations to
Site 9(Liverpool), Site 15 (Gloucestershire)
and Site 16 (Gateshead)
for recruiting the highest number of patients so far!**

The Gynaecological Oncology Research Team took part in the 100,000 Genomes Project led by Genomics England in partnership with NHS England. The project was established to



sequence 100,000 genomes from around 85,000 NHS patients affected by a rare disease, or cancer and has delivered life-changing results for patients with one in four participants with rare diseases receiving a diagnosis for the first time, and providing potential actionable findings in up to half of cancer patients where there is an opportunity to take part in a clinical

trial or to receive a targeted therapy. 6 participants from the Trust consented to take part.

Gastroenterology

The Gastro Team have had another successful year, recruiting a total of 129 participants across 4 studies and were the fourth highest recruiting Research Team within the Trust for 2018/2019.

Reproductive Health

Our Reproductive Health Team have had another successful year. They were the second highest recruiting team within the Trust for 2018/2019 with a total of 204 participants recruited across 5 studies.

The study recruiting really well is the The Helping Pregnant Smokers Quit (PREP) study, which aims to find out whether weekly phone calls, together with an e-cigarette or a nicotine patch are effective in helping pregnant women stop smoking.

The PREP study Team - Principal Investigator - Dr Vai Deshpande, Research Midwives - Christine Moller-Christensen and Rachael Grant and Data Manager - Caitlin Barry were consistently throughout 2018/2019 either Star Recruiter or Top Recruiter across the 23 UK sites taking part.

By the end of the year the Team had recruited 137 women, 22% of the overall recruitment for the UK (667 participants) which was all down to their hard work and fantastic team work between the HCA's, Midwives, Doctors and Sonographers.

The Endometrial Scratch Study (Principal Investigator - Dr Isaac Evbuomwan) appeared in QE Weekly after the study closed to recruitment in September 2018.

The Fertility Unit had taken part in the National Trial which was led by Sheffield Teaching Hospitals NHS Foundation Trust and aimed to see if gently scratching the lining of the womb, in a simple procedure called an Endometrial Scratch, could increase the rates of pregnancy during the first round of treatment.

It is not known exactly why performing an Endometrial Scratch may be beneficial, but it is thought that the process of "scratching" the lining of the womb may release certain chemicals that are important in helping the fertilised egg stick to the lining of the womb.

At Gateshead the trial was met with a positive response and 62 women took part, well above the original recruitment target of 46.

Nationally 1047 women took part in the trial across 17 sites. The results of the trial are expected to be published in September 2020.



Rheumatology

In 2018/2019, the Rheumatology Team had another successful year recruiting 186 participants across 10 studies.

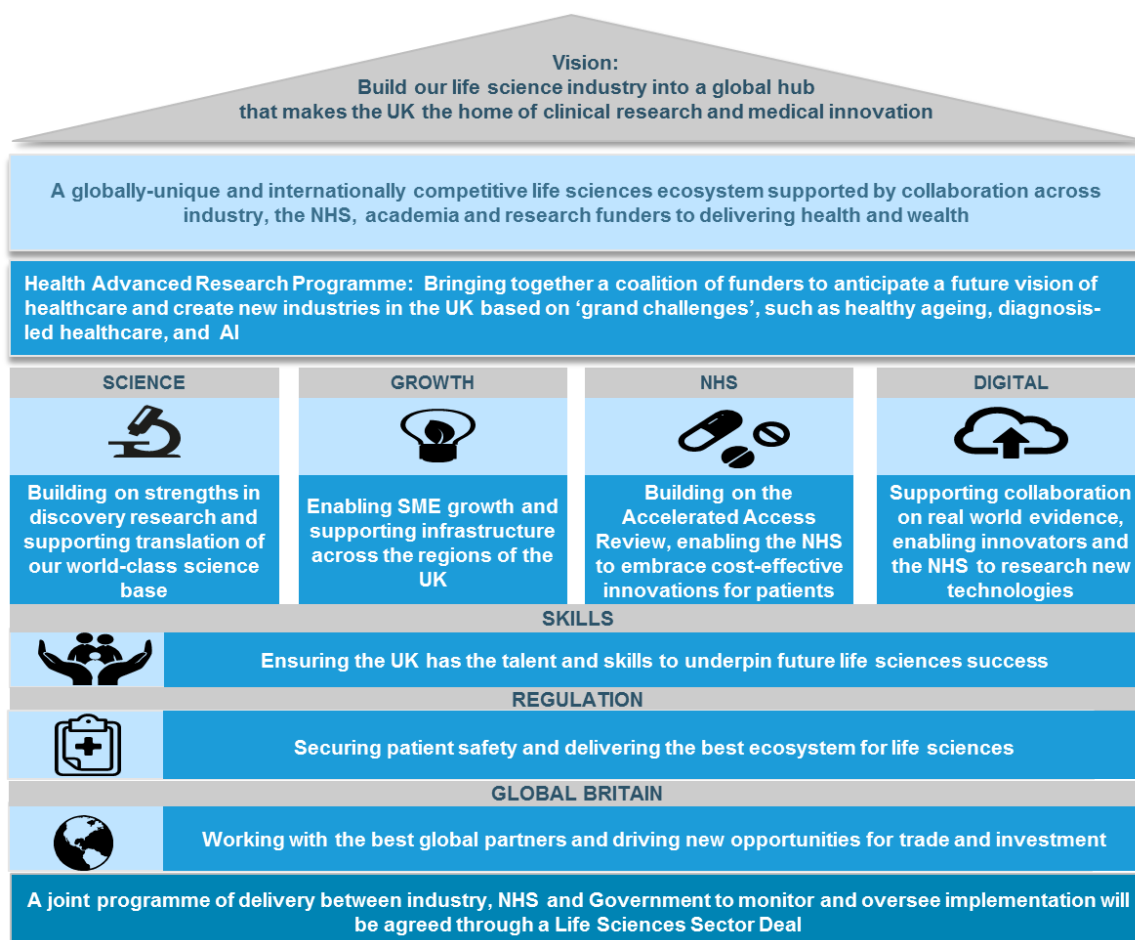
The majority of the recruitment was as a result of the GCA Study (Ear Involvement in Giant Cell Arteritis). GCA is a serious condition where arteries become inflamed (vasculitis), usually around the head and neck. Many GCA patients additionally complain about hearing loss and/or imbalance (also known as vertigo). The GCA study is designed to assess the frequency of ear symptoms in GCA patients and compare them to patients with PMR Polymyalgia Rheumatica. If a link between ear symptoms and GCA is confirmed, it may help with earlier diagnosis of GCA.

The study closed as anticipated in December 2018, but sadly the target of 500 participants wasn't achieved due to Dr Kelly retiring earlier than anticipated from research and Mrs Sue Pugmire undergoing surgery in November 2018.

A total of 317 participants were recruited in total. The final report is to be published in due course.

9. RECRUITMENT TO INDUSTRY TRIALS

The Life Sciences Industrial Strategy (published August 2017) provided a vision to build the Life Science Industry into a global hub that makes the UK the home of Clinical Research and Medical Innovation.



A key objective for the CRN NENC is to attract commercial investment to the Region, continuously improve in recruitment to time and target and increase the number of LCRN Industry active sites.

In 2018/2019 Gateshead recruited to 2 industry trials -

ESTHER (Principal Investigator - Dr Nicola Cresti) A disease Registry Study to Prospectively Observe treatment patterns and outcomes in Patients with HER2Positive unresectable locally advanced or metastatic Breast Cancer. The project is sponsored by F Hoffmann - La Roche Ltd

SANOFI DUS (Principal Investigator - Dr Jola Weaver) a drug utilization study to evaluate the effectiveness of the alirocumab dosing recommendations to avoid very low-density lipoprotein cholesterol (LDL-C) levels. The project is sponsored by Aventis Pharma Ltd, trading as Sanofi.

Speciality	Number of Industry Studies	Recruits in 18/19
Cancer	1	1
Diabetes	1	2

Gateshead Health NHS Foundation Trust was awarded a Medpace Certificate of Excellence as part of their Flagship Site Programme and is now considered a Medpace Flagship Site in recognition of our commitment to excellence in clinical research and high quality study performance.

10. RESEARCH MANAGEMENT AND RESEARCH GOVERNANCE

HRA Approval is required for all project-based research that involves NHS organisations in England where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

It brings together the assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee (REC) so that only one application is submitted.

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

11. PERFORMANCE AGAINST TARGETS AND HIGH LEVEL OBJECTIVES (HLOs)

In 2018/2019: 16 trials were submitted for confirmation of capacity and capability of these 11 (69%) were issued C&C confirmation within the 40 day target. The studies which exceeded the 40 days were due to delays resulting from contracting issues, query resolution, equipment issues and staff availability.

RESEARCH PERFORMANCE METRICS

Performance in Initiating Clinical Trials

NHS providers holding NIHR contracts issued after Autumn 2011 are required to provide, on a quarterly basis, information on recruitment to clinical trials, including commercial trials. This applies to the following studies hosted by the Trust:

- Clinical Trials of an Investigational Medicinal Product (CTIMPs)
- Clinical Investigations or Medical Device Studies
- Combined Trials of an Investigational Medicinal Product (IMP) and an Investigational Medical Device
- Other Clinical Trial studying a novel intervention or a randomised clinical trial comparing interventions in clinical practice.

In April 2018 the 70-day benchmark which measured from “Date Site Selected” (the date the Sponsor provides the local information / documentation pack to the Trust) to the “Date First Participant Recruited” was removed as a result of clinical trial performance improvement, reducing site set up and recruitment time. A new focus will be placed on transparency, accuracy and meeting sponsor expectations.

The Trust is required to publish these outcomes on the QE website and the reasons for any delays and where the responsibility for the delay sits. The reports can be viewed online at: <https://www.qegateshead.nhs.uk/research-performance>

The majority of trials not meeting the target are still due to contracting delays whereby Sponsors are not using model template agreements and a lot of time is therefore spent in negotiating / renegotiating terms.

Performance in Delivering Industry Trials

The performance in delivering clinical trials benchmark measures recruitment of the target number of patients within the agreed time (Recruitment to Time and Target) for all studies that closed to recruitment in 2018/19.

Gateshead closed 1 industry study in 2018/19.

12. NIHR RESEARCH ACTIVITY LEAGUE TABLE 2018-2019

The NIHR Research Activity League Table is published by the National Institute of Health Research (NIHR) Clinical Research Network (CRN). It shows the extent of research activity across all NHS Trusts in England, providing a picture of how much clinical research is happening, where, in what types of trusts, and involving how many participants.

This year (2018/19) the league table reveals that more than 870,250 people participated in research and had access to better treatments and care - this is the highest number of participants recorded since records began.

Jonathan Sheffield (NIHR Clinical Research Network, Chief Executive Officer) stated:-

"It's been a fantastic year for Health and Care Research across England, with 100% of Trusts supporting research studies, providing patients with more opportunities than ever before to take part in vital research which improves future treatment and care."

"The number of patients taking part in research this year is a significant step towards meeting the NHS Long Term Plan, of one million people being registered as interested in taking part in research by 2024."

"I would like to thank all those hard working, NHS staff across the country, who are supporting the delivery of research on top of their other clinical duties. We couldn't achieve these results without you."

The NIHR League Table showed that all NHS Trusts in England now offer patients, wherever they are based in the country, the opportunity to get involved in research.

Although Gateshead Health NHS Foundation Trust had an increase in the number of active research projects, there was a slight decrease in recruitment -55 participants (-4.2%) which ranked the Trust, in comparison to the other 153 Acute Trusts, as being in 105th place.

(This information has been extracted from the 447 NHS Trusts and CCG entries overall on the NIHR League Table 2018/2019)

The League Table also praised Trusts for their improved study set up and delivery - At Gateshead Health NHS Foundation Trust 69% of research studies were set up on time, delivered more efficiently and recruited to target, in comparison to last year's figure of 53%.

(The table below shows our percentage change in comparison to other Acute Trusts within the North East & North Cumbria Clinical Research Network).

NIHR RESEARCH ACTIVITY LEAGUE TABLE 2018-2019 (Table 2)

NHS Trust NENC CRN	Number of studies recruiting 2017/18	Number of studies recruiting 2018/2019	% Change	Participants in studies 2017/2018	Participants in studies 2018/2019	% Change
Northumbria Healthcare NHS FT	108	90	-16.7%	2867	3869	+ 1002 Participants (35%)
North Tees & Hartlepool NHS FT	77	87	13%	1619	2053	+ 434 Participants (26.8%)
North Cumbria University Hospitals NHS FT	42	39	-7.1%	775	826	+ 51 Participants (6.6%)
County Durham & Darlington NHS FT	97	85	-12.4%	2031	2057	+ 26 Participants (1.3%)
City Hospitals Sunderland NHS FT	140	130	-7.1%	2502	2488	- 14 Participants (-0.6%)
South Tees Hospital NHS FT	201	196	-2.5%	3740	3691	- 49 Participants (-1.3%)
Gateshead Health NHS FT	55	54	-1.8%	1298	1243	- 55 Participants (-4.2%)
South Tyneside NHS FT	44	34	-22.7%	1367	1018	- 349 Participants (-25.5%)
Newcastle Upon Tyne Hospitals NHS FT	550	501	-8.9%	16884	14051	- 2833 Participants (-16.8%)

13. Trust Open Day - November 2018

The R&D Department held a research stall at the Trust Open Day in November 2018.

Over 200 people attended the Open Day this year, which aimed to provide members of the public with a first-hand account of how the hospital treats thousands of patients every year.

The R&D Team were joined by Glyn Coupland (Physiotherapist) who was working in the R&D Department as part of a CRN NENC and Health Education England Clinical Research Awareness Course for NMAHPs.

A large percentage of our visitors this year were from local schools and colleges. They were all very keen to learn about Research and seemed genuinely interested in the projects that are currently active within the Trust. Quite a few registered their interest for work experience opportunities in R&D for 2019.



14. QUALITY IMPROVEMENT

Following on from the success with the Quality Improvement Incentive Initiative in 2017/18, the initiative for 2018/19 continued to incentivise the completion of data fields in LPMS to further increase the understanding of the work going on to set-up and deliver NIHR Portfolio studies and allowed the monitoring of the number of Investigator Initiated Trials (IITs) across the NENC Network.

The engagement and support of the Partner Organisations (POs) achieved a high level of data completeness and created an up to date information source for studies in the NENC LCRN. This ensured that the Region had the lowest error rate, just 1%, for data items in the Local Portfolio Management System (LPMS), out of all 15 Local Clinical Research Networks (LCRNs).

The three incentive criteria for 2018/19 were aligned to one or more of the Network Strategic Themes and were separated into two incentive initiatives (Table 3 below)

Table 3

Area	Criteria	Assessment
LPMS data completeness	2017/18 LPMS data completeness fields	100% data completeness for Study Set-Up and RTT data fields in LPMS from 1st April 2016 to 30th June 2018
	HLO 2A and 2B (RTT for commercial and non-commercial studies) data completed	
	HLO 4 (studies set-up within 40 days) data completed	
	Investigator Initiated Trials (IITs) recorded in LPMS	90% of IITs are recorded in LPMS (tick box) for studies where site confirmed in LPMS from 1st April 2017 to 31st March 2018. Reviewed against baseline audit undertaken by IIT work stream and reports from LPMS of studies that are commercially funded but NHS or University Sponsored.
	Pharmacy Set-Up Data recorded in LPMS	90% data completeness for Pharmacy Set-Up data fields in LPMS from 1st April 2017 to 30th June 2018

The Trust successfully achieved both phases of the Quality Improvement Incentive Criteria for 2018/2019 and in total the Trust received £11,000 of additional funding.

£6,000 of this funding went to Pharmacy, which they used to purchase a new research fridge for the Department

15. RESEARCH INCOME

During 2018/19 Gateshead Health NHS Foundation Trust received £533,135 from the NENC CRN to provide the infrastructure to support and deliver portfolio research.

This funding was allocated to support the Research Staff, R&D Department and the relevant Support Departments.

Use of this funding is reported quarterly to the CRN NENC.

£20,000 of NIHR Research Capability Funding (RCF) was awarded to the Trust.

16. PUBLICATIONS 2018/19

Over the last year, researchers from the Trust have published 54 publications (**Appendix I**). Several posters and presentations were also delivered to a wide variety of audiences.

The majority of the publications are as a result of our involvement in NIHR research, which shows our commitment to transparency and desire to improve patient outcomes and experience across the NHS.

17. FORWARD PLAN 2019/20

The Research Forward Plan sets out the priorities for 2019 / 2020 (**Appendix II**).

18. INTERNATIONAL CLINICAL TRIALS DAY 2018

Every year, the National Institute for Health Research (NIHR) promotes International Clinical Trials Day on or near 20th May. This is a special day to celebrate clinical research all over the world and to highlight the important impact research has had on medicine to date.

International Clinical Trials Day is an opportunity to shout about how fantastic research is and raise awareness of the benefits of research and the positive impact it has on people's lives.

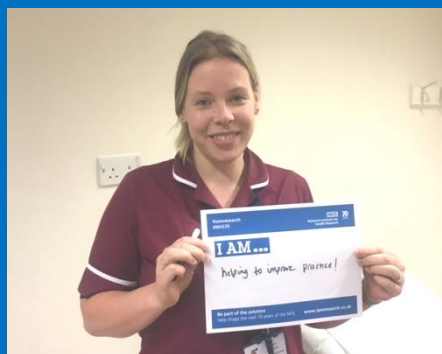
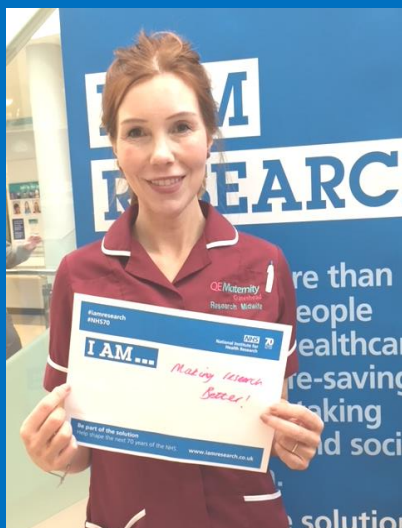


In 2018 the NHS celebrated its 70th Birthday and as part of the celebrations people were asked to “shape the NHS of tomorrow through research”.

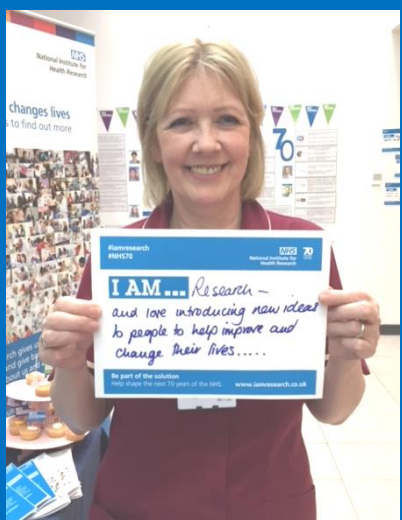
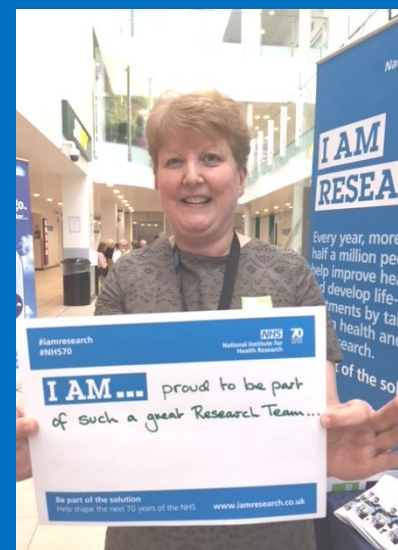
The NIHR showcased 70 Discoveries that have transformed the way the NHS works and outcomes for patients. We incorporated quite a few of the discoveries into our photo display, especially those with a connection to the Trust such as the HPV vaccine and the Tamoxifen trials for Breast Cancer.

The discoveries prompted one staff member, Sandra Bellwood, to comment that *“I was one of the first babies to benefit from the NHS born in July 1948. I have worked for the health service for 44 years and still work in procurement. I am really proud to have been part of the NHS and have seen massive changes during the past decades”*.





International Clinical Trials Day



19. CONCLUSION

This annual report has outlined the many achievements of the Research and Development team during 2018/19.

- NIHR CRN High Level Objectives – The Trust has met 5 of the 7 High Level Objectives set by the National Institute for Health Research:
 - The Trust has increased its number of studies on the NIHR CRN Portfolio
 - The Trust has increased its number of commercial studies on the NIHR CRN Portfolio
 - The Trust has reduced the time taken to set up eligible studies
 - The Trust has increased its participation in portfolio studies in new/undeveloped areas
 - The Trust has increased the number of participants recruited to DeNDRoN studies
- Quality Improvement Incentive Scheme – The CRN will set further targets regarding the Local Portfolio Management System. The Trust will need to be compliant to be eligible for the QI Incentive payments.
- The Trust will build on its increased activity within newly accessed areas; however, it also needs to explore potential new areas of research E.g. paediatrics, and medical devices and further develop genomic research.
- The R&D Department will continue to raise the profile of research within the Trust.

It is imperative that the Trust builds on its success in the future and develops our reputation as a research active Trust throughout 2019/20 as detailed in the Forward Plan.

20. RECOMMENDATIONS

The Trust Board is asked to consider and ratify this report.

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FORWARD PLAN/KEY PRIORITIES FOR RESEARCH 2019/20

Priorities	Aims
Research Management	• Maintain LPMS Research Management System • Ensure achievement of new NIHR HLOs for approval and recruitment to time and target • Submit quarterly PID data to NIHR • Deliver the NENC CRN Quality Improvement Incentive Initiative linked to LPMS • Include Research & Development in the Trust Quality Strategy • Include Research & Development in the Quality Account Submission • Deliver the Research Audit Programme • Maintain the R&D Internet and Intranet pages • Monitor the delivery of Trust sponsored studies • Continue to promote research across the Trust – attending all relevant Trust events/QE Weekly/Divisions • Discuss Trust Sponsorship of CTIMP studies with the Central Management Team • CQC – ensure that the Trust is up to date with any subsequent advice/guidance with regards to the Well-Led Framework • Northern Research Alliance – fully engage in the scoping exercise, looking at streamlining processes and working more flexibly across Gateshead, Northumbria and Newcastle • Areas of concern – capacity to run studies within certain departments, support departments nearly at capacity, room availability to recruit patients into research studies and a decrease in LCRN funding for the 3rd year in a row

FORWARD PLAN/KEY PRIORITIES FOR RESEARCH 2019/20

Priorities	Aims
Research Delivery	• Increase the number of NIHR portfolio studies recruiting across the Trust • Increase the recruitment into all of the NIHR portfolio studies • Accurate reporting in LPMS (Local Portfolio Management System) • Increase the proportion of studies recruiting to time and target • Open and recruit to more Commercial Studies • Increase the Bank Research Nurse compliment • Targeting Research According to Health Needs – COPD/Heart Failure/Diabetes (Type 1)/Mental Health (severe)/Dementia/Public Health – NE & NC CRN priority • Develop an NMAHP Research Strategy for the Trust – to encourage more NMAHP staff to take part in research – giving them an understanding of their role within research • Work Experience Students – host students and give them a grounding in research basics • Host Arc-Pep students to give them an insight into the research arena, taking their new skills and knowledge forward into the clinical areas • Horizon Scan for studies on the National portfolio – especially commercial studies • Open up new areas of research activity – Pain/A&E • Increase the Data Manager compliment
Research Finance	• Allocate resources to ensure delivery of research across the organisation • Comply with financial reporting requirements for NENC CRN and DoH for RCF • Increase the number of Industry studies to utilise the income to build capacity within the Department

APPENDIX III: GLOSSARY OF TERMS

Abbreviation	Term
C&C	Capacity and Capability
CRN	Clinical Research Network
CRN NENC	Clinical Research Network: North East and North Cumbria
CSP	Co-ordinated System for gaining NHS Permission
HLO	High Level Objective
HRA	Health Research Authority
IRAS	Integrated Research Application System
LPMS	Local Portfolio Management System
NIHR	National Institute for Health Research
ODP	Open Data Platform
R&D	Research and Development
RCF	Research Capability Funding
SOP	Standard Operating Procedure