

<b>Title</b>	Research and Development Annual Report 2014 - 15			
<b>Meeting</b>	Board of Directors			
<b>Date</b>	29 September 2015			
<b>Executive Summary</b>				
<p>Research is a core NHS activity. Being research active demonstrates a commitment to providing high quality patient care and embeds a culture of quality and innovation across the organisation. The Trust is committed to the promotion, conduct and use of research. This Annual Report outlines the Trusts research activity and performance against national targets. The report also outlines the many R&amp;D achievements in 2014 – 15</p> <p><i>The Executive Board reviewed the report and congratulated the Research and Development Team on the continuing progress and good performance being achieved across a number of specialty areas.</i></p>				
<b>Recommendation</b>				
The Board is asked to note and comment on the Research and Development Annual Report 2014-2015				
<b>Report Author</b>	Claire Livingstone, Research Lead			
<b>Executive Director/ Sponsor</b>	Dr Bob Brown, Executive Director of Nursing and Patient Safety			
<b>Purpose of paper</b>	<b>Information</b>	✓	<b>Discussion</b>	✓
	<b>Decision</b>		<b>Assurance</b>	✓
	<b>Specific action</b>			
<b>Implications</b>	<b>Staffing</b>	No		
	<b>Finance</b>	No		
	<b>Legal</b>	No		
	<b>Public engagement</b>	Yes		
	<b>Partnership</b>	Yes		
	<b>Communication</b>	Yes		
	<b>Equality &amp; Diversity</b>	Yes		
	<b>Clinical</b>	Yes		
<b>Risk assessment and mitigation (include risk register reference if appropriate)</b>				
<b>Link to STFT Business Plan</b>	Delivery of patient safety			
<b>Link to CQC outcome</b>	4 - Care and welfare of people who use services and, 16 - assessing and monitoring the quality of care			
<b>Link to Board Assurance Framework</b>	6.1 7.1			
<b>Link to Strategic Risk Register</b>				

# **Research and Development (R&D) Annual Report April 2014 – March 2015**

Claire Livingstone  
Research Lead

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## Research and Development (R&D) Annual Report 2014 – 2015

### 1. INTRODUCTION

South Tyneside NHS Foundation Trust recognises the numerous benefits of Research to the organisation and more importantly for our patients. According to a consumer poll conducted in 2013 commissioned by the National Institute for Health Research (NIHR), 87% of people would prefer to be treated in a hospital that does clinical research. Being a research active Trust demonstrates a commitment to high quality patient care and embeds a culture of quality and innovation across the organisation.

*The NHS aspires to the highest standards of excellence and professionalism...through its commitment to innovation and the **promotion, conduct and use of research** to improve the current and future health and care of the population. (NHS constitution 2012)*

2014 – 15 was a very successful year for R&D, this report outlines a number of the key achievements such as leading four portfolio trials, increasing recruitment to industry studies and winning the Chief Investigator/Study Team of the Year Award for the DISCARD II trial. This report also highlights the many research trials recruiting across South Tyneside NHS Foundation Trust and our performance against national performance metrics.

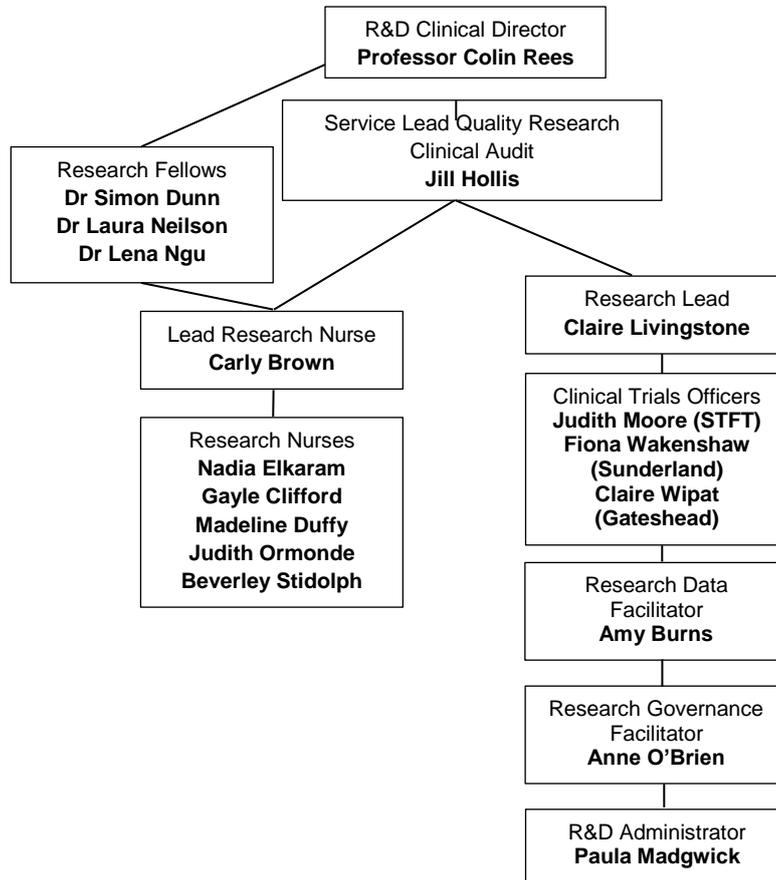
### 2. NATIONAL AND LOCAL CONTEXT

The Trust is committed to the promotion, conduct and use of high quality research. In 2006 the Department of Health established the National Institute for Health Research (NIHR) the NIHR Clinical Research Network is the clinical delivery arm of the NHS and is made up of 15 Local Clinical Research Networks. The Trust is a partner organisation of the North East and North Cumbria Local Clinical Research Network (NENC LCRN), from April 2014 the Local Clinical Research Network is made up of six divisions incorporating 30 clinical specialties (Appendix 1). The Trust works closely with the NENC LCRN to develop and deliver a range of NIHR Portfolio studies.

A number of STFT staff hold key roles in the NENC LCRN. In 2014/15 Professor Colin Rees was appointed as NENC Division 6 Clinical Research Lead (Medical) and Dr Liz Fuller was appointed Clinical Research Specialty Lead for Respiratory. Carly Brown is the Lead Gastro Nurse and Joint PPI Lead Nurse for the region. Dr Bob Brown is chair of the Research Nurse, Midwife and AHP Leadership Partnership Group tasked with developing research careers across the Region.

### 3. RESEARCH AND DEVELOPMENT TEAM

The R&D Team expanded throughout 2014/15 to meet the increased research activity and complexity of trials delivered at South Tyneside. The team comprises both clinical and non-clinical staff



The main objectives of the team are to:-

- 1) Support the delivery of research across the Trust
- 2) Increase the number of patients recruited to NIHR portfolio trials
- 3) Increase the number of studies open to recruitment
- 4) Increase our industry research portfolio
- 5) Deliver studies to time and target (achievement of the 70 day benchmark)
- 6) Develop and lead portfolio trials
- 7) Promote research and development

#### **4. RESEARCH AND DEVELOPMENT COMMITTEES**

The Research and Development (R&D) Committee meets bi-monthly and reports to the Choose Safer Care Committee which has delegated authority from the Board. The R&D Committee is responsible for leading and supporting research across the organisation, ensuring recruitment to National Institute of Health Research (NIHR) portfolio studies and ensuring compliance with the Department of Health (DH) Research Governance Framework for Health and Social Care, 2005.

The Research and Development Finance Committee meets bi-monthly. The purpose of this committee is to monitor research income and plan the resources required to deliver research across the organisation.

#### **5. RESEARCH ACTIVITY**

Research is underway in a number of clinical specialities. In 2014 – 2015, 570 patients were recruited to 41 NIHR Portfolio studies and new studies were opened in areas that previously had little or no research activity such as cardiology, critical care and anaesthesia.

**Table 1 – 2014 - 15 Recruitment by study**

*\*all recruitment figures have been taken from NIHR Open Data Platform*

Topic/Specialty Group	Study Title	Total Number of Patients Recruited 2014/15
Ageing	Reform – a randomised trial of a multifaceted podiatry intervention for fall prevention in patients over 65	79
Mental Health	SIPs Jr RCT	142
Anesthesia	A Sprint National Anaesthesia Project (SNAP) to survey patient reported outcome after anaesthesia in UK Hospitals	36
Gastroenterology	Adenoma Trial	101
	Advanced endoscopic imaging strategies for colitis surveillance	8
	Chemoprevention of premalignant intestinal neoplasia (ChOPIN) incorporating inherited predisposition of neoplasia (IPOD) analysis of genomic DNA from AspECT and BOSS clinical trial	5
	The establishment of a new generation azathioprine metabolite monitoring test based on white cells	5
	A randomised controlled trial of eicosapentaenoic acid (EPA) and/or aspirin for colorectal adenoma (or polyp) prevention during colonoscopic surveillance in the NHS Bowel Cancer Screening Programme: The seAFood (Systematic Evaluation of Aspirin and Fish Oil) polyp prevention trial	4
	Predicting serious drug side effects in gastroenterology	2
	Investigation of the clinical, serological and genetic factors that determine primary non-response, loss of response and adverse drug reactions to Anti-TNF drugs in patients with active luminal Crohn's Disease	1
	A Randomized Active-Controlled Double-Blind and Open Extension Study to Evaluate the Efficacy, Long-term Safety and Tolerability of TP05 3.2 g/day for the Treatment of Active Ulcerative Colitis (UC)	1
Cancer	Lungcast	2
	Stampede	1
	Cantalk	1
Cardiology	GLORIA - AF: Global Registry on Long-Term Oral Anti-thrombotic TRreatment In Patients with Atrial Fibrillation (Phase II/III – EU/EEA Member States)	47
Dermatology	Pressure 2	10
Health Services Research	Early evaluation of the Integrated Care and Support 'Pioneers' in the context of the Better Care Fund and the Integrated Care Policy Programme	1
Hepatology	Investigation of the Genetic and Molecular Pathogenesis of Primary Biliary Cirrhosis	4
	The Effect of Exercise on Liver Lipid in People with Fatty Liver with Moderate Alcohol Intake	3
	A UK Collaborative Study to Determine the Genetic Basis of Primary Sclerosing Cholangitis (UK-PSC)	1

Injuries and Emergencies	Tranexamic Acid for the Treatment of Gastrointestinal Haemorrhage: An International Randomised, Double Blind Placebo Controlled Trial	13
Primary Care	PCRN2761 COPD	2
	FIRST STEPS: Randomised controlled trial of the effectiveness of the Group Family Nurse Partnership (gFNP) programme compared to routine care in improving outcomes for high risk mothers and preventing abuse	7
Reproductive Health	Effect of folic acid supplementation in pregnancy on preeclampsia - Folic Acid Clinical Trial (FACT) A randomized, double-blind, placebo-controlled, Phase III, international multi-centre study of 4.0 mg of Folic Acid supplementation in pregnancy for the prevention of preeclampsia	22
	Spot protein creatinine ratio (SPCr) and spot albumin creatinine ratio (SACr) in the assessment of pre-eclampsia: A diagnostic accuracy study with decision analytic model based economic evaluation and acceptability analysis	5
	Induction of labour versus expectant management for nulliparous women over 35 years of age	2
	A randomised, double blind, multi-center, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss	2
Respiratory	A randomised, double-blind placebo controlled trial of the effectiveness of low dose oral theophylline as an adjunct to inhaled corticosteroids in preventing exacerbations of chronic obstructive pulmonary disease (TWICS)	22
	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Pulmaquin® in the Management of Chronic Lung Infections with Pseudomonas aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28 Day Open-Label Extension and Pharmacokinetic Substudy (Orbit 3)	4
	A multicentre non-blinded randomised controlled trial to assess the impact of Regular Early SPEcialist symptom Control Treatment on quality of life in malignant Mesothelioma “ - RESPECT-Meso”	2
	A Phase IIa, Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Assess the Safety and Efficacy of 28 Day Oral Administration of BAY 85-8501 in Patients with non-Cystic Fibrosis Bronchiectasis	1
Stroke	Extras	14
	Limbs Alive – Monitoring of Upper Limb Rehabilitation	3
	A Very Early Rehabilitation Trial - A Phase III, multi-centre, randomised controlled trial of very early rehabilitation after stroke	1
	RATULS: Robot Assisted Training for the Upper Limb after Stroke	1
	Reading comprehension in aphasia: The development of a novel assessment of reading comprehension	1

## **6. RESEARCH ACTIVITY BY SPECIALITY**

Research is active in several specialties and teams, the majority of research activity is concentrated in the areas outlined below

### **Cancer**

South Tyneside supports cancer research in the following tumour areas - lung, colorectal, breast, prostate renal. Recruitment to cancer trials fell in 2014 – 15; this fall in activity was anticipated due to a lack of suitable cancer studies and long delays in the set-up of new studies. It is expected cancer activity will increase in 2015 – 16 with two new trials opening; Add Aspirin and Focus 4. The Trust is working closely with the LCRN to identify suitable studies and increase resources to deliver cancer research across South Tyneside.

### **Cardiology**

South Tyneside had no cardiology recruitment in 2013/14 however during this time the team worked hard to secure new research trials and invested previous industry income to secure a part time cardiology research nurse. The team successfully recruited to the Gloria AF trial, achieving time and target recruiting 50 patients in 2014 – 15 and this trial continues to recruit well. A further industry trial Paradigm Extension is in set up and the cardiology team are currently considering other potential trials.

### **Diabetes**

It has been difficult to expand the diabetes research portfolio at South Tyneside due to a lack of suitable studies and staff changes. The Trust was previously a site in the Declining Structured Diabetes Education Study and has been invited to continue in a follow up study to look at how effective training is delivered. The Trust continues to support ADDRESS 2 and Trial Net and will continue to explore expanding diabetes research.

### **Gastroenterology and Hepatology**

Gastroenterology is the most active speciality within the Trust and the department are one of the most research active GI departments in the UK. The Trust is involved in numerous portfolio studies including industry trials. Professor Colin Rees is Chief Investigator on a number of research trials, DISCARD II closed in 2014/15 having recruited 1700 patients across the region, 309 recruited from South Tyneside. The DISCARD II trial was awarded Chief Investigator/Study Team of the Year at the Local Research Network Continuous Improvement Awards. The Trust is leading several other high quality portfolio studies;

The Adenoma Trial 'accuracy of detection using Endocuff optimisation of mucosal abnormalities' opened in December 2014/15; STFT developed the trial and are leading this trial in collaboration with Bangor CTU. The trial was funded by ARC

Medical. The trial will recruit approximately 1800 patients from seven recruiting sites including South Tyneside.

Scope-Me 'a study comparing outcomes and patient experience – PREM development' is another trial sponsored and lead by STFT. This trial is industry funded by Aquilant Endoscopy having gained the support of Crohns and Colitis UK. The two phase trial incorporating focus groups and questionnaires will actively recruit in 2015 – 16.

The Trust and University College London (UCL) secured NIHR RfPB funding to develop and lead a trial entitled 'using specialist practitioners (SSPs) to increase uptake of the bowel scope screening programme, a feasibility study of patient navigation within South Tyneside'. The trust is working in collaboration with the Bowel Cancer Screening Programme to deliver this important study.

GI are part of the NENC GI industry Collaborative, this is made up of several local NHS Trusts and has been developed to make the region an attractive site for industry studies by promoting shared passion in research and a huge combined population of patients. (Appendix 2)

### **Reproductive health and Child Health**

Recruitment in reproductive health is fairly consistent. Our previous research midwife left in 2014/15 and it has taken sometime to replace this post however with support of the LCRN we have secured some Research Midwife resource to enable the trust to continue recruitment to trials that were open. A new experienced Research Midwife has been appointed and will start in 2015 – 16. The FACT trial continues to recruit well and there are new trials expected to open in 2015 – 16.

### **Respiratory**

Respiratory has continued to develop its research portfolio and has opened a number of asthma and COPD trials. In 2014/15 the team achieved recruitment to time and target for two industry trials LEAP and FLAME and opened a further two industry trials and two portfolio trials. The team have recruited a part time Respiratory Research Nurse funded from industry income. The team have submitted several industry Expressions of Interest and have numerous trials in set up for 2015/16.

Dr Fuller has been invited to participate in a National study of COPD care: An evaluation of the effectiveness of 'care bundles' as a means of improving hospital care and reducing hospital readmission for patients with chronic obstructive pulmonary disease (COPD).

### **Stroke**

There are currently 6 actively recruiting studies, 3 ward based studies and 3 rehabilitation studies and 2 in follow up. 23 participants have been recruited to stroke studies.

The team have been successful in recruiting to the EXTRAS clinical trial evaluating a new extended stroke rehabilitation service which commences when routine early supported discharge ends.

The team continue to support RATULS, which received national attention in the media upon its launch. RATULS is a clinical trial which compares the effects of 3 types of rehabilitation treatments for the arm after stroke (usual NHS care or robot-assisted training or enhanced arm therapy programme). Collaboration with the North East Aphasia Centre at Newcastle University continues to grow promoting access to aphasia studies, enabling increased recruitment in this area of research.

### **Tissue Viability**

The tissue viability team are recruiting well to Pressure 2, consistently meeting and exceeding monthly recruitment targets. Our success in this study has been identified by the research team and the NENC LCRN. The team are keen to further expand the research portfolio and are hoping to identify suitable studies.

### **Anaesthesia**

In 2014 – 15 the Anaesthesia department were involved in the delivery of the SNAP, PROVENT and POPULAR studies. The team are very keen to take part in more research and are working with the Network to identify potential studies.

## **7. RECRUITMENT TO INDUSTRY TRIALS**

The Governments Plan for Growth in 2011 stressed that health research has a key role to play in the national economy and delivering studies to time and target is central to attracting industry/pharma to engage with the NHS. A key objective for the NENC LCRN and STFT is to increase the number of industry trials recruiting and we have seen a steady increase in industry trials and this trend is set to continue.

Year	Number of studies	Number of patients recruited
2012/13	2	18
2013/14	3	21
<b>2014/15</b>	<b>7</b>	<b>59</b>

In 2014/15 more specialities engaged in industry research than ever before with respiratory, cardiology, reproductive health and gastro all recruiting to industry trials. The respiratory team recruited to four industry trials in 2014/15 and were recognised for recruitment to time and target for two trials LEAP and Flame. Leap was a Bayer sponsored placebo controlled Bronchiectasis trial with a target to recruit 3 patients and the respiratory team exceeded this target recruiting 6 patients to time and target. Flame was a Novartis sponsored COPD Trial that achieved target recruiting four patients to time and target. The team have used a number of innovative ways to identify and engage patients holding respiratory MOT sessions in GP surgeries and advertising studies in the local press.

Our success in industry studies has brought considerable revenue into the Trust and a Commercial Income Sharing SOP has been developed to ensure this revenue is invested to further develop the trust research capabilities. In 2014/15 two nurses were employed and new equipment was bought using industry income to ensure trials could be delivered effectively.

There are a number of new industry trials in set up for 2015/16 including an international trial of gastro-oesophageal reflux disease that is expected to recruit large numbers of patients.

## **8. RESEARCH MANAGEMENT AND GOVERNANCE**

South Tyneside NHS Foundation Trust has a dedicated R&D Team to co-ordinate research delivery and Research Management and Governance. The NIHR CSP system is used to manage research approvals. The R&D team has implemented various improvements to ensure STFT achieve the CSP 15 day approval target (15 days from receipt of a valid SSI submission to NHS permission).

### **National Research Performance Metrics**

In the 2011 'Plan for Growth' the Government outlined the need for a dramatic and sustained improvement in the performance of providers of NHS Services in initiating and delivering clinical research and outlined two benchmarks against which all NHS providers would be measured

### **Performance in Initiating Clinical Trials**

The performance in initiating clinical trials benchmark monitors 70 days from receipt of a valid research application to recruitment of the first participant in the trial. The data below has been submitted to NIHR, South Tyneside opened 8 clinical trials achieving the 70 day benchmark for 6 trials (75%).

Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Comments
(FACT) Effect of folic acid supplementation in pregnancy on preeclampsia – Folic Acid Clinical Trial – A randomised, double-blind, placebo-controlled, Phase III, international multi-centre study of 0.4mg Folic Acid supplementation in pregnancy to for the prevention of preeclampsia	08/04/2014	22/04/2014	Yes	27/05/2014	14	35	49	Benchmark achieved
(FIND-UC) Endoscopic tromdal imaging vs chromoendoscopy as surveillance strategy for neoplasia in ulcerative colitis	28/04/2014	07/05/2014	Yes	27/05/2014	9	20	29	Benchmark achieved
(CRYSTAL) A prospective, multi-centre, 12-week, randomised open-label study to evaluate the efficacy and safety of glycopyrronium (50 mg od) in indacaterol and glycopyrronium bromide fixed-dose combination (110/50 mg od) regarding symptoms and health status in patients with moderate chronic obstructive pulmonary disease (COPD) switching from treatment with any standard COPD programme.	29/05/2014	03/06/2014	Yes	16/06/2014	5	13	18	Benchmark achieved
(RESPONSE) A randomised, double-blind, multi-centre, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss (RPL)	16/06/2014	19/06/2014	Yes	24/06/2014	3	5	8	Benchmark achieved
(RESPECT-MESO) A multi-centre, double-blind, randomised controlled trial to assess the impact of Regular Early SPecialist Symptom Control Treatment on quality of life in malignant Mesothelioma	09/06/2014	18/06/2014	No		9	147	156	Benchmark not achieved – no meso patients seen. 1 <sup>st</sup> patient recruited

(ORBIT-3) A multi-centre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of Pulmaquin® in the management of chronic lung infections with pseudomonas aeruginosa in subjects with non-cystic fibrosis bronchiectasis, including 28 day open-label extension and pharmacokinetic sub-study	17/07/2014	22/07/2014	Yes	31/07/2014	5	105	110	Benchmark not achieved – patient consented within 30 days but subsequently not eligible.
SIPs Jnr RCT – Developing and evaluating alcohol screening and interventions for adolescents in emergency departments	14/10/2014	16/10/2014	Yes	31/10/2014	2	15	17	Benchmark achieved
ADENOMA Study – Accuracy of Detection using Endocuff Optimisation of Mucosal Abnormalities	18/11/2014	24/11/2014	Yes	24/11/2014	6		6	Benchmark achieved
DYNAGITO - A randomised, double blind, active controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD_ exacerbation in patients with severe to very severe COPD	16/02/2015	18/02/2015	Yes	19/03/2015	2	29	31	Benchmark Achieved
FOCUS4 - Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme	19/02/2015	03/03/2015	No		12			Benchmark not achieved – no patients seen

## 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 industry studies. South Tyneside opened 4 new industry studies in 2014/15. The Response trial was closed early due to staffing problems when the Research Midwife left, Orbit 3 achieved recruitment to time and target and continues to recruit and the other two respiratory trials are still open to recruitment.

Name of Trial	Target number of patients available	Target Number of patients	Date Agreed to recruit target number of patients available	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
A prospective, multi-centre, 12-week, randomised open-label study to evaluate the efficacy and safety of glycopyrronium (50 mg od) in indacaterol and glycopyrronium bromide fixed-dose combination (110/50 mg od) regarding symptoms and health status in patients with moderate chronic obstructive pulmonary disease (COPD) switching from treatment with any standard COPD programme (CRYSTAL).	Yes	8	Yes	11/06/2015	Open		Trial extended
A randomised, double-blind, multi-centre, placebo-controlled study to evaluate the efficacy, safety, and tolerability of NT100 in pregnant women with a history of unexplained recurrent pregnancy loss (RPL) (RESPONSE)	Yes	5	Yes	15/02/2015	Open		Site closed early
A multi-centre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of Pulmaquin® in the management of chronic lung infections with pseudomonas aeruginosa in subjects with non-cystic fibrosis bronchiectasis, including 28 day open-label extension and pharmacokinetic sub-study (ORBIT-3)	Yes	3	Yes	31/03/2015	Open		Achieved
DYNAGITO - A randomised, double blind, active controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD_ exacerbation in patients with severe to very sever COPD	Yes	7	Yes	28/2/2016	Open		Trial achieved

## **9. RESEARCH INCOME**

During 2014/15 South Tyneside NHS Foundation Trust received approximately £480,000 from the NENC LCRN. This funding was allocated across the organisation to support the research infrastructure required to deliver NIHR portfolio studies. Distribution of this funding is discussed at the R&D Finance Committee and use of this funding is reported quarterly to the NENC LCRN. A further £112,000 was raised from portfolio study per patient income, recruitment to industry trials and industry collaborations with ARC Medical and Aquilant Endoscopy. £43,000 of NIHR Research Capability Funding (RCF) was awarded directly to the Trust and as lead site for the DISCARD II study the organisation received a final NIHR Research for Patient Benefit (RfPB) Grant of £25,000. Total income was approx. £671, 609.32.

## **10. CLINICAL RESEARCH FELLOWS**

South Tyneside NHS Foundation Trust has three Clinical Gastroenterology Research Fellows, the Fellows support and recruit to NIHR portfolio studies and work on the development of new national and regional studies. All Research Fellows are studying for further research degrees. In addition to research the Fellows support the Trust's gastroenterology department by playing an active role in clinical governance and provide clinic, endoscopy and capsule endoscopy support.

## **11. RESEARCH GRANTS**

In 2014/15 the Trust secured the following Research Grants

- £70, 000 from ARC Medical to develop and deliver the Adenoma Trial, this trial is delivered in collaboration with Bangor Clinical Trials Unit
- £157, 259 from NIHR RfPB to develop and deliver the Patient Navigation Trial, this trial is delivered in collaboration with University College London.

## **12. STUDIES IN DEVELOPMENT**

The OSCAR Trial 'Obesity Related Colorectal Adenoma Risk (OSCAR) Study and will be submitted to RfPB for funding

## **13. RESEARCH AWARDS**

The R&D Team have been recognised for many achievements in 2014 – 15

In October 2014 the respiratory research team received an NIHR Certificate of Achievement for successful recruitment to time and target for the LEAP trial.

In December 2014 the respiratory research team received a certificate of achievement for successful recruitment and time and target for the FLAME trial.

In February 2015, the research team received the NIHR NENC Chief Investigator/ Study Team of the Year Award for the Discard 2 Trial.

In March 2015 Professor Colin Rees was awarded the BSG Hopkins Prize in Endoscopy for his research into the early diagnosis and screening of colorectal cancer.

#### **14. PUBLICATIONS**

Uptake of Bowel Scope (Flexible Sigmoidoscopy) Screening in the English National Programme: an analysis of the first fourteen months. Lesley M. McGregor, Bernardette Bonello, Robert S Kerrison, Claire Nickerson, Gianluca Baio, Lindy Berkman Colin J. Rees, Wendy Atkin, Jane Wardl1 and Christian von Wagner Journal of Medical Screening In Press.

Patients' experience of colonoscopy in the English Bowel Cancer Screening Programme. Alex Ghanouni, Andrew Plumb, Paul Hewitson,, Claire Nickerson, Colin J Rees, Christian von Wagner. Accepted for Publication in Endoscopy Journal.

Endoscopy in 2015. CJ Rees, D Rex, P Fockens, A Emmanuel. Frontline Gastroenterology March 2015.

Factors influencing change in clinical practice: a qualitative evaluation of the implementation of the Quality Improvement in Colonoscopy Study. Praveen T Rajasekhar, Sally Brown, Catherine Nixon, Colin J Rees. International Journal of Health Care Quality Assurance. In press

Using a national screening programme to develop standardised adverse event ratios. Blanks RG, Nickerson C, Patnick J, Rees C, Rutter MD. Endoscopy Journal In Press.

Assessment and Management of the Malignant Polyp. Neilson LJ, Rutter M, Saunders BP, Plumb A, Rees CJ. Frontline Gastroenterology. March 2015.

Sedation practice and comfort during colonoscopy; lessons learned from a national screening programme . Alex J Ball, Colin J Rees, Bernard M Corfe, Stuart A Riley. European Journal of Gastroenterology and Hepatology. In press

What do patients want from their endoscopy experience? The importance of measuring and understanding patient attitudes to their care. M Tierny, R Bevan, CJ Rees, T Trebble. Frontline Gastroenterology. May 2015.

A multi-centre pragmatic study of an evidence based intervention to improve adenoma detection: The Quality Improvement in Colonoscopy (QIC) study. PT Rajasekhar, CJ Rees, MG Bramble, DW Wilson, MD Rutter, BP Saunders, APS Hungin, JE East. Endoscopy Journal February 2015.

Prospective, multi-centre case-control study to evaluate the safety, acceptability and accuracy of the Cytosponge. TFF3 test for diagnosing Barrett's esophagus. Caryn S.

Ross-Innes, Irene Debiram-Beecham, Maria O'Donovan, Elaine Walker, Pierre Lao-Sirieix, Laurence Lovat, Michael Griffin, Krish Ragunath, Rehan Haidry, Philip Kaye, Marco Novelli, Babett Disep, Richard Ostler, Benoit Aigret, Bernard North, Pradeep Bhandari, Stephen Attwood, Anjan Dhar, Adam Haycock, Danielle Morris, Colin Rees, Matt Rutter, Peter Sasieni and Rebecca C. Fitzgerald. PLOS Medicine January 2015

Patient derived measures of GI Endoscopy: A meta-narrative review of the literature. Sally Brown, Roisin Bevan, Greg Rubin, Catherine Nixon, Simon Dunn, Simon Panter, Colin J Rees. Gastrointestinal Endoscopy. In Press.

Neilson LJ, Bevan R, Panter S, Thomas-Gibson S, Rees CJ. Terminal ileal intubation in routine colonoscopy practice. Expert Reviews of Gastroenterology and Hepatology 2015;12:1-8

Gill MD, Bramble MG, Hull MA, Mills SJ, Morris E, Bradburn DM, Bury Y, Parker CE, Lee TJ, Rees CJ. Screen-detected colorectal cancers are associated with an improved outcome compared with stage-matched interval cancers. British Journal of Cancer 2014;111(11):2076-81

Geraghty J, Butler P, Seaman H, Snowball J, Sarkar S, Blanks R, Halloran S, Bodger K, Rees CJ. Optimising faecal occult blood screening: retrospective analysis of NHS Bowel Cancer Screening data to improve the screening algorithm. British Journal of Cancer 2014;111(11):2156-62

Dhar A, Close H, Viswanath YK, Rees CJ, Hancock HC, Dwarakanath AD, Maier RH, Wilson D, Mason JM. Biodegradable stent or balloon dilatation for benign oesophageal stricture: pilot randomised controlled trial. World Journal of Gastroenterology 2014;20(48):18199-206

Bevan R, Rubin G, Sofianopoulou E, Patnick J, Rees CJ. Implementing a national flexible sigmoidoscopy screening program: results of the English early pilot. Endoscopy 2014 (Epub ahead of print)

Bevan R, Lee TJ, Nickerson C, Rubin G, Rees CJ; NHS BCSP Evaluation Group. Non-neoplastic findings at colonoscopy after positive faecal occult blood testing: Data from the English Bowel Cancer Screening Programme. Journal of Medical Screening 2014;21(2):89-94

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## **15. CONCLUSION**

This annual report has outlined the many achievements of the research team; key achievements being:-

- Increase in recruitment to industry trials
- Rapid expansion of industry research in respiratory medicine and the achievement of recruitment to time and target for two trials
- Receiving the Chief Investigator/Study Team of the Year Award for DISCARD II
- Leading and coordinating the delivery of the Adenoma Trial across several sites

The research portfolio at South Tyneside continues to expand and we anticipate record recruitment in 2015 – 16.

## **16. RECOMMENDATIONS**

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

## **17. FORWARD PLAN 2015/2016**

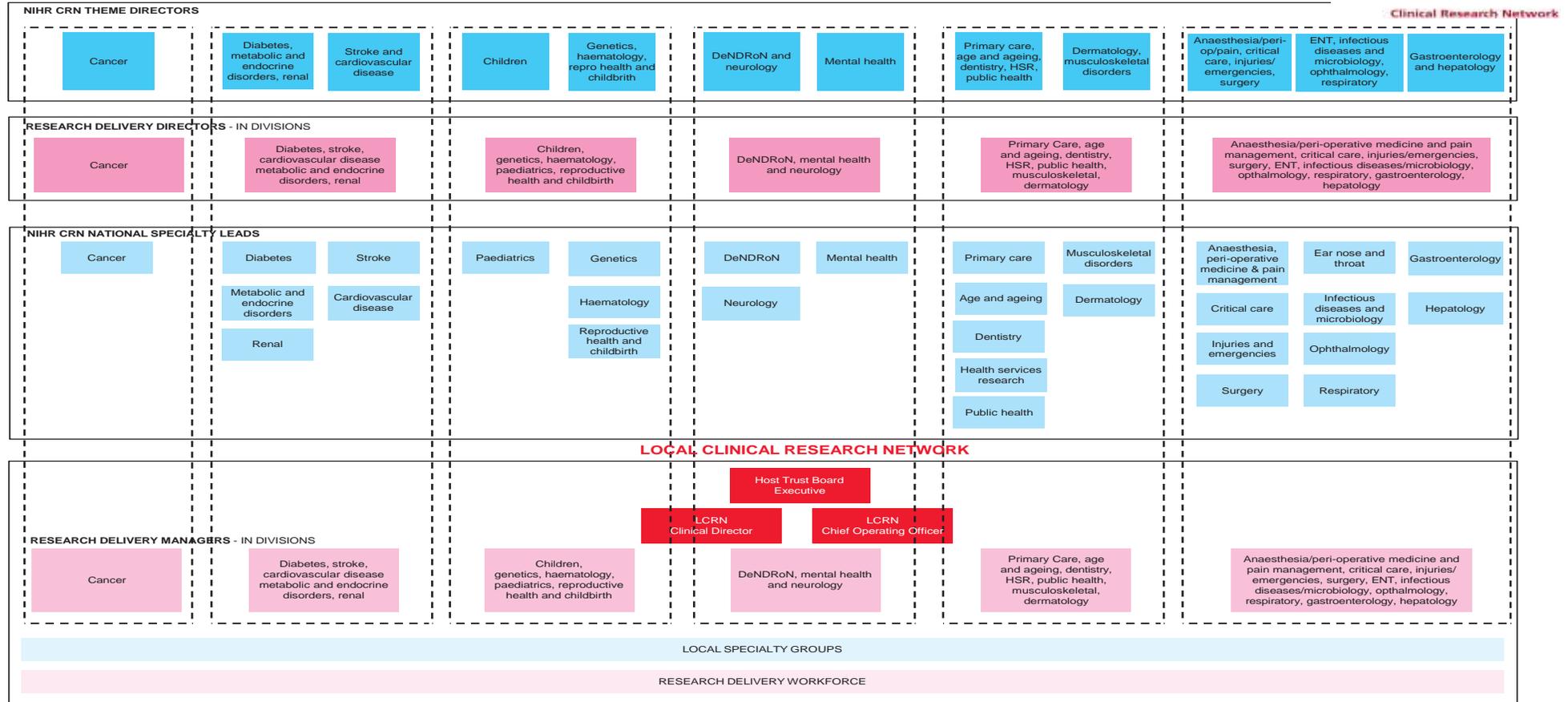
The Research Forward Plan sets out the priorities for 2015-2016

## Forward Plan/ Key Priorities for Research 2015 – 2016

Priorities	Aims
Research Management and Governance (RM&G)	<ul style="list-style-type: none"> <li>• Implement HRA roll out, amending processes and procedures accordingly.</li> <li>• Ensure 15 day approval target is maintained</li> <li>• Submit quarterly PID data to NIHR</li> <li>• Update and develop relevant SOPs</li> <li>• Plan and deliver RM&amp;G audit programme</li> <li>• Update the R&amp;D Internet and Intranet pages</li> <li>• Add R&amp;D to Trust App</li> </ul>
Research Delivery	<ul style="list-style-type: none"> <li>• Increase the number of NIHR portfolio studies recruiting across the Trust</li> <li>• Increase the proportion of studies recruiting to time and target</li> <li>• Promote research across the Trust</li> <li>• Implement ReDa the NENC LCRN Local Portfolio Management System across the Trust</li> <li>• Continue implementation of the research strategy</li> <li>• Support the develop of the programme of research activity linked to the Integrated Care Hub</li> <li>• Lead and sponsor new portfolio trials, for example OSCAR</li> </ul>
Research Finance	<ul style="list-style-type: none"> <li>• Allocate resources to ensure delivery of research across the organisation</li> <li>• Comply with financial reporting requirements for OuR and RCF</li> <li>• Monitor industry income and utilise in line with Industry finance SOP</li> <li>• Deliver the NIHR CRN: Continuous Improvement Incentivisation Scheme</li> </ul>

# Appendix 1

## STRUCTURE FROM APRIL 2014: NIHR CRN specialties, themes and research delivery divisions



## Appendix 2

# *NENC GI Industry Collaborative Newsletter*

### *Why a collaborative?*

There is a huge potential to increase the industry research that we perform. The collaborative will facilitate this because of two certainties:

- a) That sponsors (pharma and CROs) are regularly frustrated by inefficiency of study site set-up and the recurrent failure of sites to recruit to time and target (RTT). Any improvements we can offer are enthusiastically received.
- b) We have already shown that we work well as a collaborative and that, between us, we have a huge population patients eligible for trials.

### *Why bother with industry research?*

- Because it is a priority for the NIHR and for UK plc.
- Because it matters to our patients. They value having access to new treatments and they perceive that units which are involved in clinical trials of new treatments are high achieving.
- These studies make a difference to clinical care. They are much more likely to do so than own-account research.
- Industry research brings in funding which helps to build research infrastructure. This is going to become increasingly important as NIHR/CRN funding becomes increasingly stretched.
- Publications and collaborations are often offered to investigators who recruit well.

### *How does the collaborative make a difference?*

#### ***Benefits for sponsors***

- Access to a large population of patients for clinical trials
- Negotiations through a single clinical lead and senior industry manager
- Unified approval mechanisms, single costing template negotiation and coordinated SIVs / monitoring
- Accurate feasibility delivered through an engaged process of consultation which includes experienced PIs and senior industry manager
- Internal performance management

### *Benefits for clinicians*

- Attract more studies
- Broaden capability – more centres and more PIs
- Greater responsiveness
- Joint intelligence and mutual support
- Shared targets (= greater resilience)
- Developing a brand (through performance management and achievement of targets)

### *Progress to date*

The initiative was launched on 29<sup>th</sup> January 2015 and the response from sponsors has been remarkably positive. The CRN has been very supportive providing a funded leadership role for Yan Yiannakou and 0.4wte of dedicated time from Jemma Fenwick to augment the support provided by the industry team. We have made progress at refining our multi-site EOI process and single costing template negotiation.

Since launch we have considered 12 studies for the collaborative, of which 8 were potentially eligible and expression of interest questionnaires were submitted to industry for consideration. Of these so far, 2 studies, Rhythm and GORD have progressed into the set up stage at more than one organisation with the aim to open recruitment by the summer and an aspiration of recruiting the first UK patient. The Rhythm study of diabetic gastroparesis is an important study which was not going to be run in the UK before the sponsor heard of our collaborative. The GORD study is a simple study but should recruit >150 patients from our region and show that we can succeed at high volume recruitment.

We are waiting outcome of feasibility application for the other six studies and are working to improve the distribution of studies around the region, with new sites and PIs being involved e.g. Northumbria, James Cook and Cumbria.

### *Tips for getting involved and recruiting well*

- Be open to the possibility. This is a real opportunity to be involved in something that is growing.
- Sub-specialist clinics. These are key to good recruitment.
- Keep databases (make sure these are secure and approved by data managers)
- Don't delay! As soon as you put in your EOI start looking for patients.
- Get colleagues to help. Put the word out and keep reminding colleagues of key eligibility criteria.

### *IBS database*

There are IBS studies coming along in the next few years but the problem is that we often discharge patients. Please ask your patients if we can contact them for future trials (consent for contact) and if they agree send a copy of the clinic letter to Yan Yiannakou marking it **for database**. We will input data to a secure database. You will be able to retrieve that data when the trials become available.