

Clinical Research Network
North East and North Cumbria



*National Institute for
Health Research*

MEDConNecT North

connecting NHS and Technology in the North East and North Cumbria

Performance Financial Year 2016/17

28th April 2017

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1. Introduction

The MedConNecT North service has been running since 2015/16, the aim of the service is to bridge the gap between Med-tech SMEs and the NHS to support bespoke medical technology research projects. The service is constantly evolving to meet the demands and needs of the companies that request support and to maintain relevance with national priorities.

The service also provides NHS and Academic staff help in order for researchers to connect with relevant Industry to partners and develop Investigator Initiated Trials (IITs).

The service began without any defined baseline activity or understanding of the requests that would be received. The first two FYs 2015/16 and 2016/17 enabled the group to obtain a proportion of this data. The group set the following targets for 2016/17 (a 10% increase on the previous FY) however it is clear from the data gathered to date that a sustainable, high quality and consistent service that is both responsive and relevant is far more valuable to the region and service users:

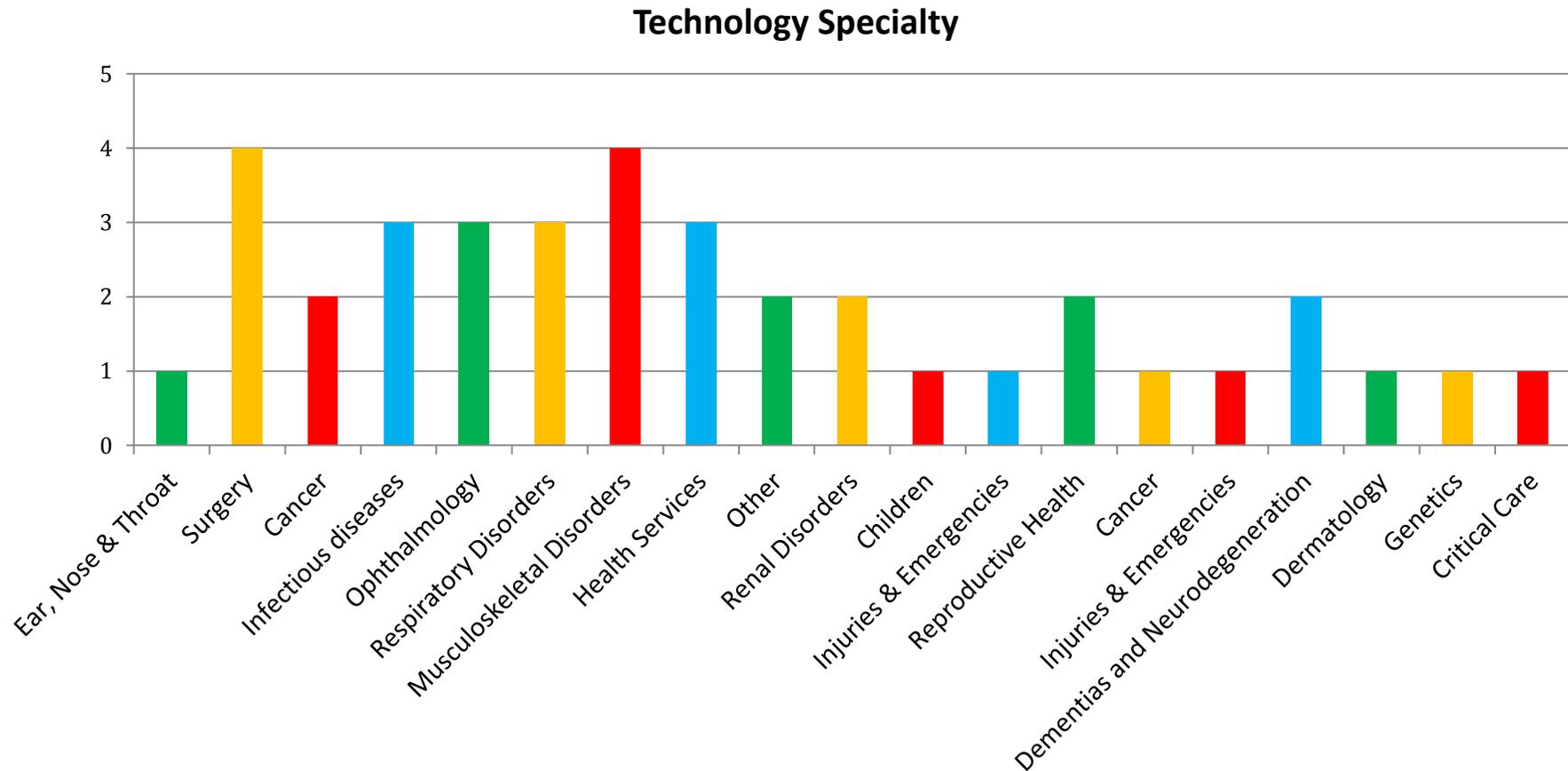
- 47 Interactions with new companies
- 56 Industry projects requiring bespoke support
- Supporting 5 members of NHS staff and continuing to support Academic staff from 3 or more Universities
- Bespoke support conversion rates – 60% or above
- 10% increase in open commercial NIHR portfolio medical device studies within NENC – 20 studies
- 10% increase in open non-commercial NIHR portfolio medical device studies within NENC – 29 studies
- 1 project converted to a collaborative grant application
- Total feasibility response rate – 70% or above

2. Performance

Industry

MedConNecT North interacted with 38 companies in 2016/17. Unlike the previous financial year each company focused solely on one priority technology/project meaning the group supported 38 projects. The projects continue to be diverse in nature and target patient population, covering a range of NIHR Specialties.

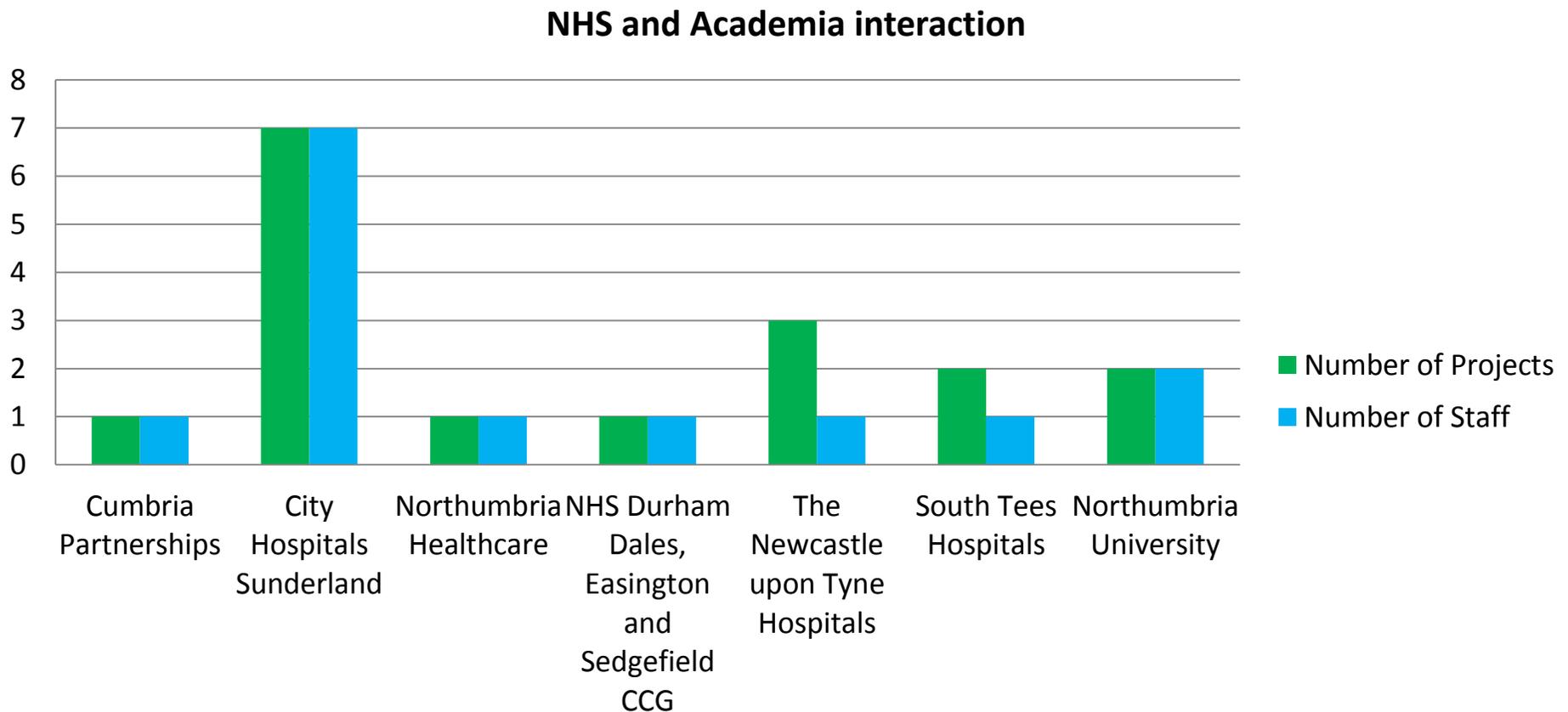
Chart 2.1 - Projects supported by MedConNecT North by specialty



NHS & Academia

The chart below details the number of NHS and Academic staff requesting MedConNecT North supported in 2016/17. MedConNecT North supported 12 NHS staff with 15 projects, including 5 local NHS Foundation trusts and 1 local CCG. They also supported 2 members of academic staff. This is a substantial increase on the previous year, where there were only 4 NHS Staff and 8 projects supported.

Chart 2.2 - NHS Staff and Academia Interaction



Bespoke Support Conversion Rate

In 2016/17 MedConNecT North supported 55 projects in total, both commercial and non-commercial

- 34 Initial projects requests have been met and delivered:
 - 23 are still underway
 - 6 studies are currently in set up (4 commercial and 2 non-commercial)
 - 5 successfully completed (including 1 commercial and 1 non-commercial study)
- 8 Projects are still ongoing
- 13 project requests were not met and unsuccessful

Conversion Rate: 62%

Increase in NIHR Portfolio “Medical Device” Studies

The table below shows the number of both commercial and non-commercial studies open and recruiting on the NIHR portfolio in the NENC region.

Open NIHR Portfolio Studies	2015/16	2016/17
Commercial (Med-tech)	18	25
Non-Commercial (Med-tech)	29	31

Specifically, MedConNecT North has initiated new activity that has led to 13 Med-Tech studies since April 2015:

- 9 studies in set-up (4 commercial and 5 non-commercial (IIT))
- 1 open NIHR commercial study
- 3 closed studies (2 NIHR commercial studies, 1 non-commercial study)

Grant Applications

In 2015/16 there was limited grant application activity supported by the group, hence a low target to increase to 1 was applied. 2016/17 was a really successful year for grant application submissions and MedConNecT North supported/helped to facilitate 7 grant applications to the following bodies*:

- NIHR Innovation for Invention (i4i)
- Horizon 2020 (H2020)
- Small Business Research Initiative (SBRI)
- NIHR Research for Patient Benefit (RfPB)
- Arthritis UK (ARUK)
- NIHR Efficacy and Mechanism Evaluation (EME)

In 2016/17 MedConNecT North invested in access to the ResearchConnect Funding database.

The group can now search for funding opportunities and applicable grant bodies on behalf of the NIHR Clinical Research Networks (CRN) Partner Organisations (POs) and SMEs.

To date over 60 searches have been ran on behalf of companies and local POs with the hope that this will generate future applications in 2017/18.

*(*The increase in grant application activity was largely down to company interactions from the previous FY)*



Response Rate

- 139 “pre-feasibility requests” were sent out
- 55 “Expressions Of Interest” (EOIs) were received from NHS sites around the region, to help with the development of medical technology projects in collaboration with Industry
- 42 “Investigator declined” responses were received, sites felt it wasn’t suitable to collaborate with industry on these specific projects

Total response rate: 70%

3. Discussion

2016/17 has proven to be another very successful second year for MedConNecT North.

Factors that occurred in year that may need to be considered when risk assessing in future include:

- Changes in infrastructure. The MedConNecT North group restructured mid-year and new members were not appointed until the new FY 17/18. The group now has 6 members, consisting of 4 consultants, 1 Operations Manager (Med-Tech) and 1 part time administrator.
- In 2016/17 the group applied a more rigorous triage process to ensure the projects taken forward were of a research focus and relevant to the aims and the objectives of both the group and CRN: NENC.
- In 2016/17 MedConNecT North made referrals to other regional organisations that sit under the Academic Health Science Network's (AHSN) Innovation Pathway Partners to ensure companies could still receive necessary support where relevant.
- Going forward the group will need to continue to work well the CRN: NENC Industry team, namely the Clinical lead and IOM to help develop and deliver the attracting investment to the region strategy area of the 2020 vision (https://drive.google.com/drive/folders/0B5zXj4_jWSASdjZ0NmJJTEd5a2M)

4. 2017/18 – Targets

At the end of 17/18 MedConNecT North will assess the data generated over the previous 3 financial years. This will allow the group to look at patterns and understand the key areas to focus on in order to establish sustainable and effective aims and objectives.

It is therefore important that the 2017/18 targets reflect maintenance of a consistency and high quality service, that delivers the needs of the service users.

- Minimum of 30 Interactions with new companies looking to develop their technologies through clinical research
- Supporting 10 or more NHS/Academic led projects
- Bespoke support conversion rates – 60% or above
- Sustaining or Increasing open commercial NIHR portfolio medical device studies within NENC
- Sustaining or Increasing open non-commercial NIHR portfolio medical device studies within NENC
- 5 grant applications to be supported or facilitated
- Total feasibility response rate – 70% or above

Baseline Data to also be collected in the 2017/18 FY:

- Number of projects that have been supported which have led onto an Investigator Initiated Trial (IIT)
- Number of referrals onto other partners within the AHSN's Innovation Pathway

Case Study 1

The 'Tookie Vest for Renal'

CASE STUDY CATEGORISATION

Service: SME Interaction

Innovation Pathway: MedConnect (LEAD); Med Physics NUTH, R&I Sunderland

Research: IIT, Non Comm NIHR Portfolio Research

NHS Organisations: CHS, NUTH

SG: Renal



In early 2016 MedConNecT North introduced Tookie to Dr Saeed Ahmed, Consultant Nephrologist at City Hospitals Sunderland.

The meeting considered the potential of adapting the Tookie vest, originally designed to prevent inadvertent catheter fall out in paediatric oncology patients, for use in adult HaemoDialysis (HD) patients. An adapted vest would hopefully be able to support patients fitted with a Central Venous Catheter (CVC) to provide enhanced line security and patient well-being in treatment – 'A life more normal'.

Vascular access is essential for providing adequate haemodialysis, which is ultimately a life-saving therapy. Complications of CVC use are well documented especially that of catheter displacement and gravitational pull caused by excessive body tissue mass; with one in ten patients affected.



Each line re-instatement costs the NHS approximately £3,000.00, whilst also affecting the patient's quality of life.

City Hospitals Sunderland's renal research team (Dr Saeed Ahmed, Dr Rachel Davison, Paul Corrigan and Debbie Sweeney) and the Research and Innovation (R&I) department (Mr Kim Hinshaw, Lynne Palmer and Emily Brand) supported by

MedConNecTNorth subsequently arranged for the Tookie team to hold patient centred focus groups to re-design the vest and create an adaptable product that could be used within this patient population. Focus groups took place between May

2016 and March 2017. In this time the vest has developed across several prototypes with the final design now ready for trial.

Dr Thomas Beale, Clinical Scientist within the Medical Physics department (The Newcastle upon Tyne Hospitals NHS Foundation Trust) has also recently engaged with the project to provide both regulatory and methodological support and guidance.

The next step currently underway is the design of a proof of concept pilot study. The multi-centre study will aim to explore the un-met need of the renal patient to provide a suitable wearable vest to improve their Quality of Life (QoL) and enhance mechanisms that enable the efficient delivery of their treatment. The study will also assess the impact of the garment on clinical outcomes i.e. fall out rates.

The impact of this regional collaboration will be used to inform the need for a larger clinical study which will hopefully in turn inform NICE guidelines. Most importantly, a multi-centre research study will allow all suitable patients in the region equity of access to the new vest. It is hoped that this will positively impact the patient experience and enhance their quality of life. The study will also be put forward for the National Institute of Health Research (NIHR) portfolio adoption.



Dr Saeed Ahmed and all the team at City Hospitals Sunderland have proactively supported the collaboration over the last year and the patients have kindly dedicated their valuable time and support also.

City Hospitals Sunderland is uniquely placed in the North East and North Cumbria Nephrology community to undertake such collaborative work. This is due to the Renal department's interest in "Interventional Nephrology" and vascular access service. They have over the last few years developed an extensive experience in the field of CVC technology and insertion that is second to none in the region. Specifically, Dr Ahmed holds a council position in the Vascular Access Society of

Britain and Ireland (VASBI) and regularly feeds back on novel CVC technology to manufacturers. Dr Ahmed has also published articles looking at the prevention of displacement of CVC. A recent paper can be found here: <https://www.ncbi.nlm.nih.gov/pubmed/26349889>

The North East and North Cumbria Tookie case study is a great example of the collaborative capabilities of the region and the ability to support Small and Medium Enterprises (SMEs) with medical technology research, development and evidence generation.



Case Study 2

The GEKO Study

CASE STUDY CATEGORISATION

Service: SME Interaction

Innovation Pathway: MedConnect (LEAD); R&I JCUH

Research: Comm NIHR Portfolio Research

NHS Organisations: JCUH

SG: Injuries & Emergencies

Firstkind Medical developed the GEKO device, which when first brought to market was used in the prevention of DVT. Since then the company have developed the device for use in oedema associated with injury and surgery.

The team at Firstkind Medical were keen to evaluate the device's effectiveness in reducing the swelling caused by ankle fractures, in order to allow surgeons to operate earlier, thus resulting in a shorter hospital stay for patients and savings to the NHS.

MedConNecT North put FirstKind Medical in touch with a trauma and orthopaedic consultant at James Cook University Hospital. The concept was reviewed and thorough feedback was provided to the company on how best to run the trial, factors to be considered, background information that was required, costs to be analysed etc.



The collaboration has resulted in an NIHR portfolio a pilot study, conducted at James Cook University Hospital, ran by Mr Paul Baker and his research team. The study will be used to inform the design of a full RCT to generate robust meaningful research to inform national and international practice with widespread adoption of the device.

This was Mr Baker's first commercial study and the team hit 100% RTT recruiting a total of 20/5 patients.



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