



**National Institute for
Health Research**

Clinical Research Network
North East and North Cumbria

MEDConNecT North

Progress Report

September 2015

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Delivering research to make patients,
and the NHS, better

1) Introduction

A pilot regional working medical technology group was established in November 2014, jointly funded by the NIHR Clinical Research Network: North East and North Cumbria (CRN: NENC) and the Academic Health Science Network North East and North Cumbria. (AHSN NENC). The medical technology group comprises NHS clinicians, with expertise in medical technology research covering a range of specialties, LCRN industry staff (providing managerial and administrative support):

- Professor Sam Eldabe, Clinical Professor of Anaesthesia and Pain Medicine
- Professor Yan Yiannakou, Consultant Neurogastroenterologist
- Mr Anirvan Banerjee, Consultant ENT Surgeon
- Professor Amar Rangan, Consultant Orthopaedic Surgeon
- Professor Nick Linker, Consultant Cardiologist
- Dr Andrew Turley, Consultant Cardiologist
- Dr Tony De Soyza, Respiratory Physician
- Morag Burton, NIHR CRN: NENC Industry Operations Manager
- Rachel Forrest, NIHR CRN: NENC Industry Manager
- Amanda Goodman, Academic Secretary, Trauma and Orthopaedic Surgery

The group have aligned their key objectives to ensure they map to the High Level Objectives set by NIHR CRN, and in particular, building on our strengths as a region to ensure we are at the forefront of innovation, to maximise patient health outcomes and the regional economy. The objectives also complement the Wealth Creation programme of AHSN by assisting with the delivery of the Innovation Pathway. The Innovation Pathway has been developed to map services aimed at improving the economy of the region by creating wealth and job opportunities, as well as improving the health and wellbeing of the region as a whole. More information on the innovation pathway can be found at:

http://www.ahsn-nenc.org.uk/wealth_programme/innovation-pathway/

The group's strategy is to work towards establishing NENC as a national leader for supporting Small and Medium Enterprises (SMEs), and other medical device manufacturers, innovation and medical technology development (hereafter referred to as 'industry'). To do this the group acts as a conduit between industry and the NHS, facilitating early expert feedback and peer review, supporting product development, facilitating product evaluation and clinical research and providing guidance and advice on other key areas such as regulatory approvals, adoption processes and dissemination.

2) Objectives

Contractual objectives were set by AHSN NENC. The table below demonstrates objectives met to date. (Appendix 1 lists the deliverables and outcomes to date in further detail)

Timescale	Deliverable
01/11/14 - 31/01/15	Establish a working group
01/11/14 - 31/01/15	Develop a communication strategy
01/11/14 - 31/01/15	Establish regular group meetings
01/11/14 - 31/01/15	Establish a working relationship with NHS Innovations North
01/11/14 - 31/01/15	Establish a working relationship with National Office of Clinical Research Infrastructure (NOCRI)
01/11/14 - 31/01/15	Establish a working relationship with BAREMA
01/11/14 - 31/01/15	Establish a working relationship with NIHR Diagnostic Evidence Cooperative Newcastle
01/11/14 - 31/01/15	Establish a working relationship with External Assessment Centre, Newcastle Hospitals
01/11/14 - 31/01/15	Establish a working relationship with Innovations department/eye infirmary, Sunderland Hospital
01/02/15 - 30/07/15	Develop an E-Newsletter
01/02/15 - 30/07/15	Provide 5 regional SMEs with bespoke support
01/02/15 - 30/07/15	Identify obstacles to medical technology research in the region
01/02/15 - 30/07/15	Establish a medical technology policy
01/02/15 - 30/07/15	Local mapping of SME pipeline
01/02/15 - 30/07/15	Generate worked examples/case studies of bespoke support
01/05/15 - 30/10/15	Meet Bi-Monthly with AHSN
01/05/15 - 30/10/15	Organise a medical technology seminar/conference
01/05/15 - 30/10/15	Regular attend Speciality Group meetings with NHS staff/clinical experts
01/05/15 - 30/10/15	Early stage trial set up and /or prototyping development.
01/05/15 - 30/10/15	Co-applicant status on NIHR and other grants

 Met

 Further work needed

 Not met

3) Key achievements

A summary of MedConNecT North's achievements:

3.1) Interactions

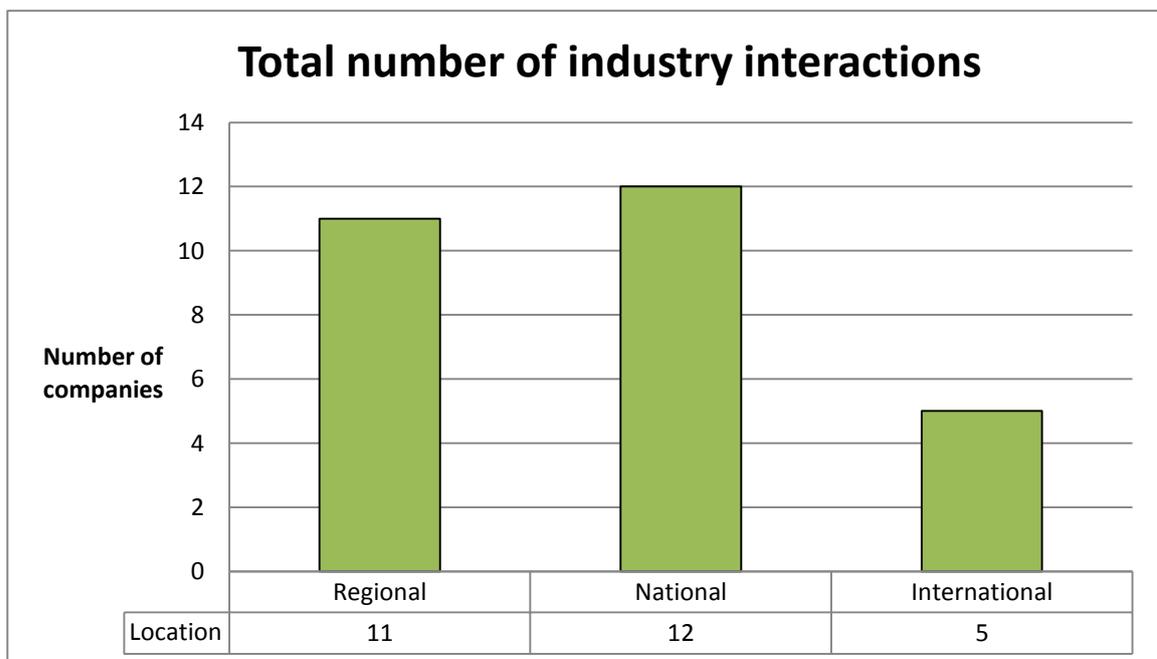
One of the main objectives above was to identify and initiate the provision of bespoke support to at least five regional SMEs. The charts below demonstrate the group's activity to date, which is expected to increase significantly after the launch event.

Chart 1 shows the level of interaction between MedConNecT North and industry according to geographical location. An interaction can be defined as:

- The referral of a company into MedConNecT for support from another organisation (i.e. AHSN NENC)
- MedConNecT North group members establishing a relationship with a company and supporting their projects
- MedConNecT North supporting existing industry contacts with new projects
- MedConNecT North supporting companies with NIHR portfolio studies
- MedConNecT North support companies via direct approach

A project can be defined as ideas, prototypes or technology that require early feedback/review, development, evaluation or support with adoption/diffusion. (Appendix 2 details current case studies and provides more in depth information relating to the interactions highlighted below).

Chart 1 - Level of interaction between MedConNecT North and industry



As well as working with industry the group has interacted with both NHS clinicians and Academics to develop their ideas. Interactions have so far involved South Tees Hospitals NHS Foundation Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University.

Chart 2 shows the number of projects MedConNecT North has supported and their corresponding medical specialty.

Chart 2 – Number of projects supported by medical specialty

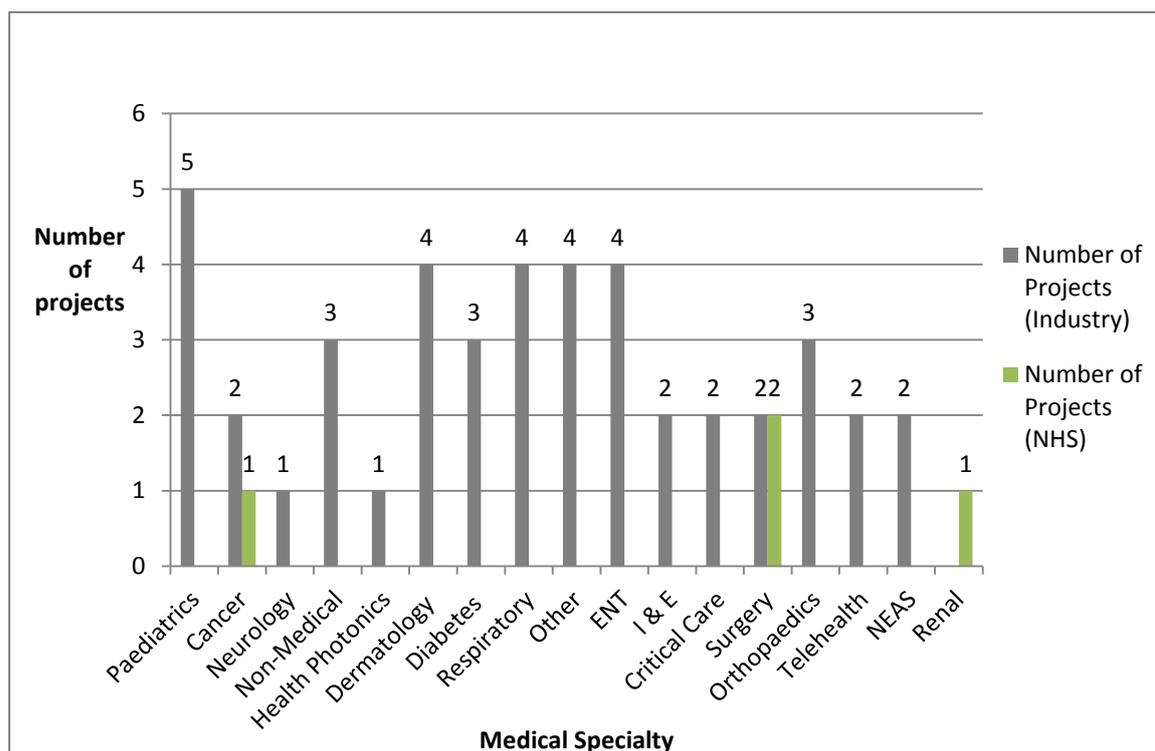
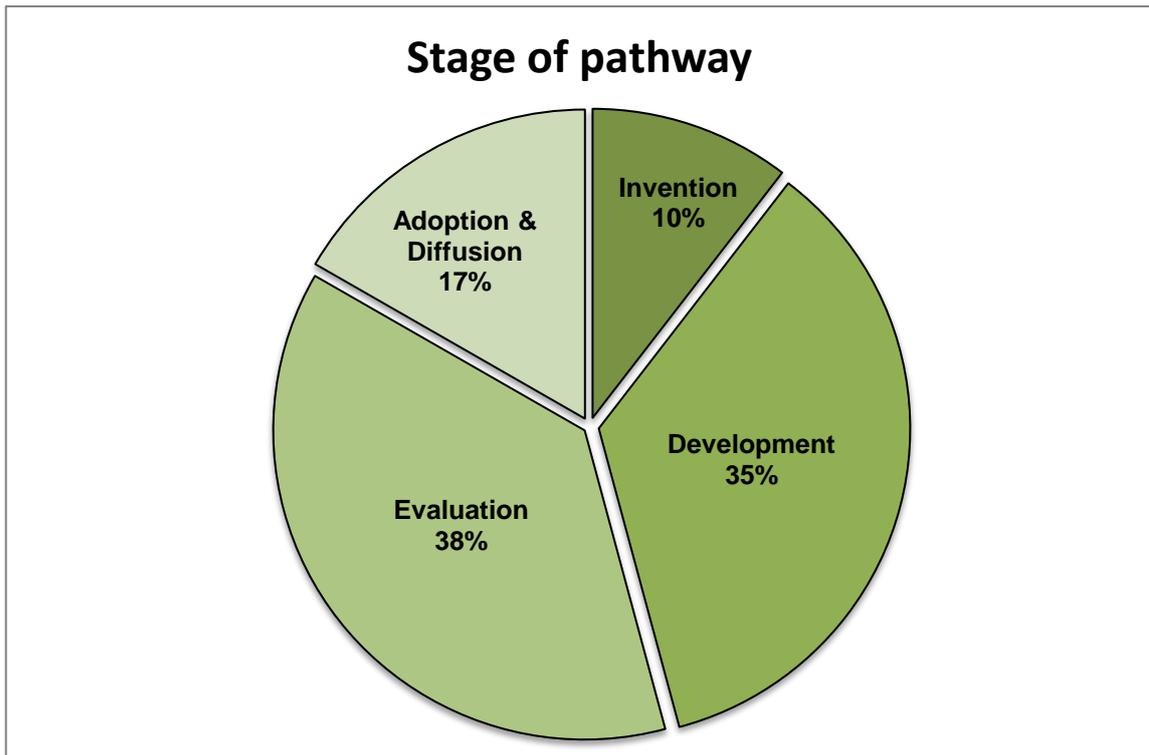


Chart 3 describes the stages of the medical technology pathway MedConNecT North has facilitated support. The medical technology pathway is made up of a series of stages that projects must go through to take the technology from concept to widespread adoption. These include: - Invention of technology, Evaluation of technology, Adoption of technology, diffusion of technology. (Appendix 3 lists the stages of the pathway in further detail).

Chart 3 - Stage of the pathway MedConNecT North facilitated support



Summary of impact to date:

- Bespoke service has been provided to a higher than expected number of regional companies within a short time frame. MedConNecT North has also sustained this level of service on a national level, even expanding to international companies.
- The diverse range of specialities shows that there is scope within the medical device sector to innovate, develop products and engage with industry across multiple specialities, POs and grow our industry portfolio as a region.
- The services of MedConNecT North have already been utilised across each section of the medical technology pathway, however this will require continuous monitoring to further identify the groups significant strengths and areas for improvement to maximise the quality and efficiency of work.
- MedConNecT North needs to assess how to become visible and approachable by innovative clinicians across all POs as there is clearly scope in this area.

3.2) Raising our profile

The established group members meet on a 6 weekly basis and early discussion has centred on raising the profile of the group. Progress made so far includes:

Branding

The group has been established as MedConNecT North, to represent the connection the group facilitates between NHS, academia and industry. The branding demonstrates the group's capacity to cater for commercial and non-commercial needs throughout the medical technology pathway (see appendix 3).

Website

The website highlights the capabilities of the group on a professional and interactive level. The main purpose of the site is to allow users open access to all aspects of the medical technology pathway (see appendix 3) via one route. (www.medconnectnorth.com)

Event

MedConNecT North is hosting an event in September 2015. This event will be the official launch of the group and the aim is to ensure MedConNecT North is known to industry on a local, national and international level. The presence of NHS staff, academic staff and other key organisations will showcase the group's ability to engage industry with the contacts they seek and vice versa.

3.3) Connecting

Successfully raising the profile of the group requires buy in from key organisations and those who play a major role in the medical technology pathway. On a national level the group are connected with The Department of Health (DoH), National Institute for Health and Clinical Excellence (NICE) (medical technology evaluation programme), NIHR National Office for Clinical Research Infrastructure (NOCRI), NIHR Health Technology Co-operatives (HTCs), NIHR Diagnostic Evidence Co-operatives (DECs) and NIHR Clinical Research Network Coordinating Centre (CRNCC). A key focus for the group moving forward will be to sustain these relationships and continue to establish pathways whereby referrals between organisations can be made. On a local level the group have engaged successfully with Partner Organisations (POs) establishing a process with R&D managers for referrals and connections with clinicians. A similar process has been established with Business Development Managers (BDMs) within local universities and Specialty Group (SG) Leads within CRN: NENC. The medical technology industry manager role is embedded within the CRN: NENC industry team allowing MedConNecT North to capitalise on existing successful industry connections and relationships with research active clinicians/staff. The tables below highlights the number and type of connections made so far and the scope of further connections still to be established.

Table 1 – Key meetings

Key Meetings	Progress to date
R&D Manager's within PO's	10/13
Research Delivery Managers	6/6
Clinical Leads	3/6
Speciality Group (SG) Leads	14/30
SG meetings attended by medical technology industry manager	12

Table 2 – Connections with key organisations

Other connections made with key organisations
Clinical Leadership Group
NHS Innovations North/RTC North
Regional GP Forums
NIHR Devices for Dignity
North East of England Commissioning Support
National Office for Clinical Research Infrastructure (NOCRI)
Department of Health (DoH)
The National Institute for Health and Care Excellence (NICE)
Health Technology Co-operatives (HTCs)
NIHR Diagnostic Evidence Co-operatives (DECs)
NIHR Clinical Research Network Co-ordinating Centre (CRNCC)
Business development at Newcastle University, Northumbria University & Teesside University

The group have identified a medical technology champion in 3 of the 6 divisions. Division 2 is CRN Lead Nurse, Kevin Short, Division 3 is CRN Lead Midwife, Fiona Yelnoorkar and Division 6 is Speciality Group Team Lead (North) Sean Scott and Speciality Group Team Lead (South) Rachel Clarkson. Divisions 1, 4 and 5 are currently working on appointing a champion. It is hoped that the champions will encourage and embed the work of the group within their specialties. The champions will also help the group identify new clinicians that would like to engage with both research and innovation.

4) Continuous Improvement

The group aims to establish its work as a national exemplar by demonstrating a thorough understanding of the medical technology pathway. The group must be proactive in nature to align with the fast paced environment of the medical technology sector. The group have therefore established an internal services timeline to demonstrate their capabilities throughout the medical technology pathway (<http://medconnectnorth.com/pathways-timeline/>). The group continues to establish connections with key organisations to ensure MedConNecT North is a single point of entry for all users. An internal referral process has also been designed to allow the group to triage enquiries and allocate cases to group members on a specialty basis (see table below). This process currently works well however it is expected that the volume of enquires will rise significantly after the launch event and an ongoing review process needs to run in parallel to ensure this method of working is the most efficient.

Table 3 – Group member speciality allocation

Speciality	Assigned Member	Speciality	Assigned Member
Cancer and Cancer (Paediatrics)	AB	Dermatology	YY
Cardiovascular Disease	AT/NL	Musculoskeletal Disorders	AR
Diabetes	AT/NL	Oral and Dental Health	YY
Metabolic and Endocrine Disorders	AT/NL	Primary Care	YY
Renal Disorders	AT/NL	Anaesthesia, Peri-op & Pain	SE, AR
Stroke	AT/NL	Critical care	AR
Children	SE, YY	ENT	AB
Genetics	SE	Gastroenterology	YY
Haematology	SE	Hepatology	YY
Reproductive Health and Childbirth	SE	Infectious Diseases and Microbiology	AB
Dementias & Neurodegeneration	SE	Injuries & Emergencies	AR
Mental Health	SE	Ophthalmology	AR, YY, A B
Neurological Disorders	SE	Respiratory Disorders	AB
Ageing	AB	Surgery	AR, YY

(Key: Anirvan Banerjee (AB), Amar Rangan (AR), Andrew Turley (AT), Sam Eldabe (SE), Yan Yiannakou (YY))

5) Future developments and potential impact

The regular group meetings provide an opportunity for members to highlight key areas for expansion or improvement. Throughout the last 6 months it has become apparent that the group need to establish metrics in order to measure success and work collaboratively with other organisations in order to offer a truly unique bespoke service: -

Metrics and targets for MedConNecT North

The group aims to devise a sustainable business plan that will allow MedConNecT North to become self-funding. Therefore it is imperative suitable sources of funding is identified and secured in the very near future.

Income generation as a direct result of support from MedConNecT North will need to be assessed to monitor the economic impact the group provide to the region. This should be subject to a target % increase year on year. However since no baseline data currently exist this particular metric will need to be specifically developed by the group in forthcoming meetings.

The group has agreed to set targets for MedConNecT North to monitor productivity. Since November 2014 the group have assisted 5 companies that are now in trial set up, 80% of which will be commercial portfolio studies, 1 company is currently collaborating with NHS clinicians on a grant proposal and various other companies are very early on in the process with clear opportunities to progress to evaluation.

With this in mind, the launch of the website and the launch of MedConNecT North formally in September the group propose the following areas to target:

- Number of interactions with companies per Financial Year (FY)
- Number of industry projects requiring bespoke support per FY.
- 30% increase in open commercial NIHR portfolio medical device studies within NENC per FY – (Baseline 14/15 = 10 open studies).
- Number of NHS/Academic staff requiring bespoke support per FY
- 10% increase in open non-commercial NIHR portfolio medical device studies within NENC per FY - (Baseline 14/15 = 7 Investigator Initiated Studies and 5 non-commercial studies).
- Number of projects converted to collaborative grant applications
- Bespoke support conversion rates (%) – successful outcomes per all bespoke requests

The above metrics should be subject to a % increase year on year to demonstrate growth and success of MedConNecT North.

Funding Opportunities

Funding is an area SMEs struggle to source and furthermore apply for. The group has connected with leading national funding bodies (Invention 4 Innovation (I4I), Small Business Research Initiative (SBRI) and innovation organisations (Knowledge Transfer Network (KTN)) to overcome this hurdle. The group are also supported by NHS Innovations North and NENC AHSN in helping regional SMEs secure funding. Links have also been made with leading academics to assist with grant writing for collaborative projects. The collection of income data will allow the group to establish the progress of these connections.

Clinical Research Organisations (CROs)

Often SMEs do not have budgets to fund CROs to help support their projects. As such they struggle with protocol writing, regulatory approvals, patient documents etc. The group have therefore sourced 4 potential companies with the capability to offer small scale CRO services to SMEs. It is intended that the group will outsource specific CRO services to each company to make this process more affordable and efficient for SMEs.

6) Challenges and Risks

The work of the group is new, and unique on a national scale. In particular therefore maintaining continuous support from clinicians and POs may prove challenging. It is hoped that through the group's contacts, links with SG leads and one to one meetings MedConNecT North will continue to be supported across the region.

MedConNecT North will have to ensure they remain visible to all potential service users going forward. This challenge has been addressed at group meetings and action plans are currently being devised to ensure the group is actively promoted. Actions include: - increasing search-ability of the website via google, active promotion via local and national communications, partnering with industry at the forefront of innovation to jointly deliver mutual aims and objectives and actively seeking key connections with organisations likely to require and/or support the services of MedConNecT North.

The group will need to continually assess capacity and resource to maintain efficiency and to continuously deliver high quality support. It is expected that workload will increase after the launch event in September therefore the group must ensure standard operation procedures and robust processes are in place to successfully deliver an efficient service and meet the above targets.

The group are able to escalate issues via CRN: NENC risk register, allowing action plans to be devised where appropriate.

Appendix 1 – Contractual obligations

Timescale	Deliverables	Outcomes
1 st November 2014 to 31 st January 2015	Develop a medical technology working group; appoint staff / resource for the medical technology group as well as agreeing which clinical staff to be involved.	Group Established (November 2015)
	Develop a communications strategy for the medical technology group illustrating the types of services available and how these can be promoted to regional medical technology SMEs. Also, identify where these services fit within the overall service offering provided by the AHSN NENC.	Services Established (Feb 2015) Standalone website to promote services (May 2015) NOCRI and DoH agreed to promote on a national level (April 2015) The group is highlighted as part of AHSN NENCs innovation pathway (ongoing)
	Organise a series of meetings of the medical technology group, ensuring that attendance includes all of the Partner Organisations of the AHSN NENC.	1 meeting held (February 2015). Scheduled to meet every 6 weeks with AHSN NENC invited to all meetings. (ongoing) AHSN NENC innovation pathway PO meetings scheduled. (ongoing)
	Liaise with NHS Innovations North to gain intelligence of the local SME network.	Medical technology industry manager met NHS Innovations North (December 2014 and ongoing)
	Cross reference the activity of the medical technology group with NHS Innovations North, the National Office for Clinical Innovations (NOCRI) and BAREMA (http://www.barema.org.uk).	NHS Innovations North (December 2014 and ongoing) NOCRI (January 2015 and ongoing) BAREMA (December 2014, need to establish ongoing relationship)
	Develop an understanding of the other Partner Organisations of the AHSN NENC, such as the NIHR Diagnostic Evidence Cooperative, the External Assessment Centre (both provided by The Newcastle upon Tyne Hospitals NHS Foundation Trust), City Hospitals Sunderland NHS Foundation Trust Eye Infirmary and NHS Innovations North.	Medical technology industry manager met with all (February 2015). Innovation Pathways PO meetings (as above).
1 st February 2015 to 30 th April 2015	Launch first edition of an e-newsletter and develop face to face communications with regional SMEs, develop ongoing dialogue and content for the newsletters.	MedConNecT North feature in NENC LCRN monthly newsletter (ongoing), however need to establish an internal monthly newsletter for our website
	Identify, and initiate the provision of support to at least five regional SMEs that require bespoke support from the medical technology group.	Support is being provided to multiple SMEs (Ongoing- see following tables)

	Identify the obstacles to medical technology research in the region and establish a medical technology policy.	Regular review of challenges at MedConNecT North group meetings. Internal processes are being established in order to develop a definite medical technology policy (Ongoing). The group can also escalate issues to CRN: NENC executive meetings via the risk register.
	Local mapping of the pipeline of medical technology SMEs.	The group have established a working spreadsheet which maps SME interaction (ongoing)
	Map relevant interests and publish these as commercial sensitivities allow with the AHSN NENC website.	Case studies are recorded and will be published via MedConNecT North's website (Ongoing). These case studies will also be made available to AHSN NENC.
1 st May 2015 to 30 th October 2015	Regular updates to be provided at bi-monthly meetings with the AHSN NENC.	Bi-monthly meetings held with AHSN NENC (ongoing).
	Organise a medical technology seminar for the North East and North Cumbria region to showcase the developments to date, preferably in conjunction with the AHSN NENC Partner Organisations. Invite relevant stakeholders from the MHRA, notified bodies, NICE medical technology committee, representatives from North Cumbria, clinical researchers, HEI academics and regional, national and international SMEs. This Seminar should have a target audience of at least 30 industry representatives.	Event organised and sold out (July 2015). Attendee split: 67 Industry, 40 NHS, 16 Academic, 37 Other (including notified bodies, HRA, Funding bodies etc).
	Host and fund an event to showcase the capabilities of the medical technology group to regional SMEs and other industry partners.	See above
	Capture Speciality Groups / NHS experts and SME / medical technology interactions as categorised by the following: - Attendance at Speciality Groups meetings as well as face to face meetings with SMEs; Co-applicant status on NIHR and other grants for example, SBRI, MRC, DPFS etc current or those planned within 12 months; and Early stage trial set up and /or prototyping development.	SG meetings documented as above. Further progress demonstrated in the following charts.

Appendix 2 – Case studies



Stage of Pathway – Evaluation

Summary – Bio-signatures are running a phase 1 feasibility study to collect video recordings of cystoscopy examinations to enable the development of a prototype of the recording device and software enhancement system. Assuming the outcomes of the phase 1 study are positive, the evaluation will then progress to a much larger validation study of the technology.

Impact – MedConNecT North were able to offer advice about NIHR portfolio adoption and the phase 1 study is now going ahead as a commercial portfolio study. The group were able to advise how best to run a multi-site study and identified sites within the NENC region that would contribute to a larger validation study.



Stage of Pathway – Evaluation

Summary - BeneChill International GmbH successfully ran the COOLHEAD1 study in North Cumbria University Hospitals NHS FT. This was a pilot study that looked at a new way to treat migraines through nasal cooling. Results showed that 87% of patients benefited from the treatment.

Impact – Due to the success of COOLHEAD1 within the NENC region the company approached MedConNecT North to identify sites to run their COOLHEAD2 study. Set up for this is now underway in North Cumbria. The group assisted BeneChill with the study submissions and although the study was not adopted onto the commercial portfolio, they received support throughout the set up process and enabled the set up to be carried out within a short time frame.

Stage of Pathway – Invention, development and Evaluation

Summary – MedConNecT North met with Consultant Paul Ballard from South Tees NHS Foundation Trust who was hoping to develop two surgical devices. Mr Ballard had previously struggled to progress both projects without bespoke support due to clinical and academic commitments.

Impact – MedConNecT North and Mr Ballard set up regular monthly meetings to ensure progress of the projects. As a result a small pilot study has been designed for one of Mr Ballard's innovations and is currently in set-up at James Cook University Hospital with dedicated support from their R&D department. MedConNecT North has provided a protocol assessment, regulatory approval guidance and general support throughout the project. MedConNecT North has also referred Mr Ballard into NHS Innovations North so both projects can be supported from an Intellectual Property (IP) perspective. MedConNecT North has linked Mr Ballard with South Tees Medical Physics department based at James Cook University Hospital to support the development of the second project. Regular meetings between MedConNecT North, R&D and Mr Ballard continue to date to ensure both projects progress successfully and in a timely manner.

POLYPHOTONIX

Stage of Pathway – Invention and Evaluation

Summary - PolyPhotonix are a local company who possess world leading capabilities in printed electronics. They have several potential therapeutic applications of LEDs/OLEDs emitting specific wavelengths of light from within flexible materials (e.g. blankets, dressings), however were not sure which areas to focus on and which would be of the greatest benefit to NHS patients. PolyPhotonix not only needed NHS insight and expertise that would help with this particular aspect of their portfolio but it was recognised that a successful collaboration could lead to the development of longer term relationships and delivery of high quality clinical trials. In addition the team at PolyPhotonix were in a position to evaluate a medical device, Noctura 400 sleep mask, used for the treatment of diabetic retinopathy.

Impact – MedConNecT North put PolyPhotonix in contact with multiple NHS consultants who gave early expert advice in multiple areas of application. As a result the team at PolyPhotonix were able to concentrate on the projects that appeared to offer the highest impact to the NHS in terms of patient benefit and cost effectiveness. The group also assisted the company with the set-up of their study 'CANDLE' evaluating the Noctura 400 sleep mask which was successfully adopted onto the NIHR portfolio. James Cook University Hospital, Middlesbrough is a key participator in this trial.

Stage of Pathway – Adoption & Diffusion

Summary – Coveris are a large international manufacturing company. They develop products within multiple markets including food, medical and security. MedConNecT North met with a representative from their local office in Hartlepool. Coveris had 3 particular products they were hoping to place in the NHS: - Secure, tamper evident security patient property storage, standardised mailing bags and tamper evident, sterile pharmacy packaging. Coveris were hoping to have these products adopted for use in the NHS.



Impact – MedConNecT North contacted multiple departments in various trusts to identify any interest in the above products. Coveris are now linked with City Hospitals Sunderland (CHS). CHS's Innovation Manager and Scout introduced Coveris to their procurement department and subsequent meetings have since taken place. Although Newcastle Hospitals didn't identify a need for the products within their trust they did however refer Coveris onto the NHS Supply Chain.

Stage of Pathway – Invention and development

Summary – Quality Hospital Solutions (QHS) is a local SME based at NET Park, Sedgefield. QHS have a collaboration agreement with City Hospitals Sunderland (CHS) NHS Foundation Trust and as such act as their commercial arm when developing innovation within the trust. QHS work with staff within CHS to help develop their ideas and innovations. Both QHS and CHS have regularly requested the assistance of MedConNecT North to help with the set-up of early feasibility/pilot trials, in particular looking for guidance on regulatory requirements and trial design. QHS have also requested the assistance of MedConNecT North to facilitate connections with other NHS Trusts within the region.

Impact – MedConNecT North put QHS in contact with the Business Development team at County Durham and Darlington NHS Foundation Trust (CDDFT). The two organisations are now in advanced discussions to try and establish a way to replicate the CHS model at CDDFT. If this proves successful MedConNecT North will assist QHS in establishing a similar model with other trusts across the UK. This will help to expand and grow the QHS business and firmly embed the company as an NHS product development partner. MedConNecT North continues to support QHS and CHS in their early feasibility trial work and give guidance where appropriate. A small pilot study of a urological device is now in the process of being set up at CHS aiming to inform the need for a larger Randomised Control Trial (RCT) which can be set up across multiple sites in the region and be adopted onto the NIHR portfolio.

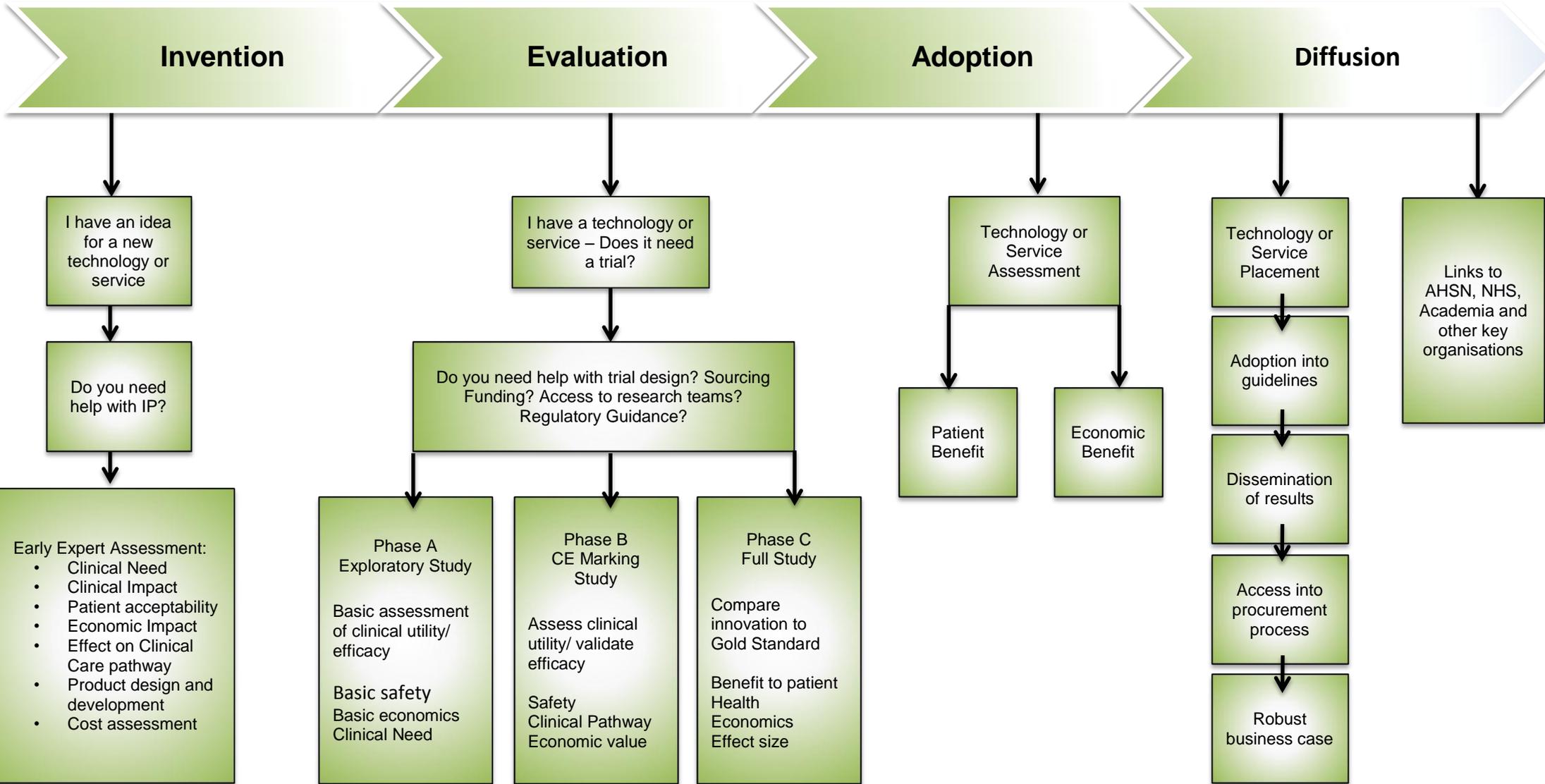


Stage of the Pathway – Development and Evaluation

Summary – MedConNecT North met with Rocket Medical in June 2015. They are developing a range of medical devices across multiple specialities but don't have direct access to expert clinicians that can assist with early product review/feedback from an NHS perspective. They also identified that support might be needed in the form of evidence gathering or field testing and as such running clinical trials to evaluate their products.

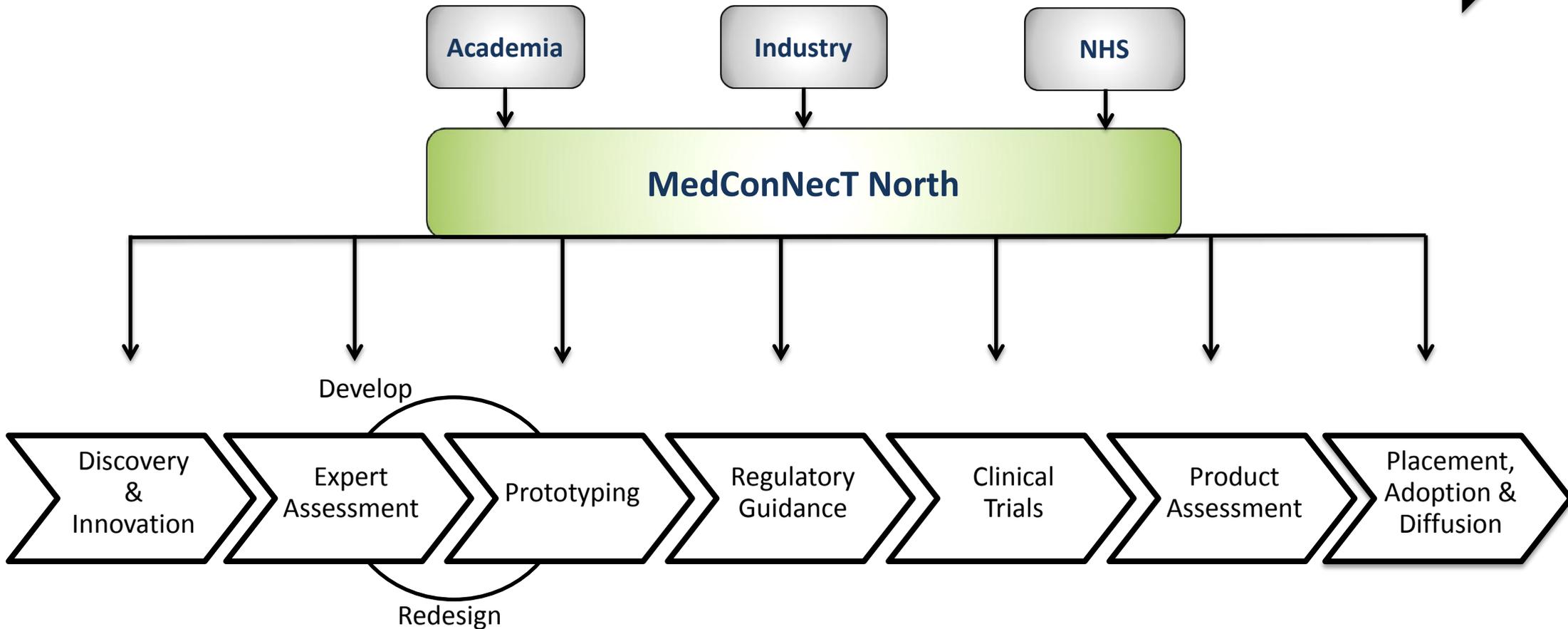
Impact – The group requested access to a group of midwives/labour ward staff to increase their understanding of labour ward equipment and use. MedConNecT North facilitated a meeting between the team at James Cook University Hospital and Rocket Medical. From the meeting, Rocket Medical identified ways to develop innovation further in this speciality and will work collaboratively with the department going forward. MedConNecT North also introduced Rocket Medical to a Neonatal consultant and the Innovations team from CHS. The meeting proved mutually beneficial as they discussed devices in the neonatal field as well as establishing ways that Rocket Medical can support CHS in their innovative research moving forward. MedConNecT North introduced Rocket Medical to the North East Ambulance Service to help the team progress the development of a new ambulatory pneumothorax device Pleural Vent and finally the team at Rocket Medical are now linked with Dr Tony De Soyza, Respiratory Consultant at Freeman Hospital, to discuss devices within this speciality.

Appendix 3 - Stages of the medical technology pathway



Appendix 3 continued - Illustration of MedConNecT North Services

MedConNecT North offer advice and guidance along the pathway. Signposting to key organisations where applicable and providing valuable links and access to experts within the NHS, Academia and Industry.



Discovery & Innovation – The Group work closely with key organisations that help protect early ideas and discovery. The group also establish the nature of the innovation and signpost accordingly to ensure you receive the best advice as early as possible.

Expert Assessment/Prototyping – Provide Industry with access to NHS consultants for early expert assessment and linking NHS staff with Industry for expert advice in design and manufacture. Enabling essential feedback in some of the following areas to assist with early development:

Clinical Need	Patient acceptability
Clinical Impact	Effect on Clinical Care pathway
Economic Impact	Product design and development

Regulatory Guidance – Including CE Marking, Research Ethics approval, MHRA, Insurance and local R&D policies.

Clinical Trials – As well as offering expert clinical trial advice, the MT Group can also signpost to further assist in this element of the pathway.

Clinical Trial guidance includes:

Evidence gathering – what is required

Type of trial needed

Trial design and methodology

Sourcing Funding

Patient and Public Involvement

Health Economics

Access to National NHS Consultants

Set-up support

Product Assessment – Signposting to enable the assessment of patient and economic benefit.

Placement, Adoption & Diffusion – Links to Academia, NHS and other key organisations for report writing, dissemination of results, assistance with product placement, adoption into guidelines and planning a robust business case.



***National Institute for
Health Research***

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North East and North Cumbria

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