SBRI Phase 1 Application Form

Created: 07/13/2016
Last updated: 07/27/2016

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Required fields are noted with an *

1) Description of Proposed Idea/Technology *

Please provide a brief description of your proposed idea/technology and how this addresses the customer need, market and patient problems. Include how you plan to engage key stakeholders in Phase 1. Please consider defining the market/patient you plan to address; the implications, size, cost of the problem and market. Outline your solution and how it meets the market/patient needs, including the needs described in the competition category brief, how it could be implemented, cost of doing so and any other matters arising from its adoption. To support this description you may upload an image file by using 'Upload Proposal Document(s)' Task, which is available from the Main Application task menu. (500 word limit)

UNMET NEED
Many diseases of children are related to the child's ability to oxygenate their blood. For example children with asthma, cystic fibrosis, congenital heart defects, obstructive sleep apnoea, bronchiolitis, sickle cell anaemia and neonatal lung conditions are some diseases which can lead to more severe morbidity (e.g. brain damage) or death if oxygen levels are not monitored and appropriate action (e.g. oxygen therapy) taken. The unmet need of suitable solutions to monitor oxygen levels in paediatric patients was identified by the Technology Innovation Transforming Child Health (TITCH) Network and was an unmet need at an innovation workshop supported by the Y&H AHSN. The project described in this application is an output of the innovation workshop.

The clinical needs can be broken down into two areas -diagnosis and monitoring.

1. Diagnosis: In primary care probes used are often the wrong size or used incorrectly leading to over referral to secondary care. An improved technique for accurate assessment in primary care will aid decision making thereby leading to reduced admissions to hospital.

2. Monitoring: Current techniques used for home monitoring are cumbersome and not optimised

for movement. This leads to a lack of compliance and/or inaccurate readings.

THE SOLUTION

The project is to develop a wearable , self-adjustable wireless probe (with appropriate paediatric software algorithms) that can be used in children. The wearable technology solution can aid in decision making thereby leading to reduced admissions to hospital and during home monitoring lead to improvements in independence and self-management for children requiring long-term oxygen or home ventilation therapy.

MARKET OPPORTUNITY

The objective of the project is to develop solutions for the paediatric market. However the wearable technology solution is also applicable to adult markets such as chronic obstructive pulmonary disease (COPD) (according to GBI Research the global market for COPD is currently worth $11.3 billion).

Although the wearable technology will be appropriate to a number of children with other long term conditions, as an indication of the market the opportunity for asthma alone is provided. In the UK there are 5.4 million people (including 1.1million children (I in 11 children). Every 10 seconds one person in the UK is having a potentially life threatening asthma attack with everyday in the UK 3 people dying from asthma. (latest data shows that in 2014 forty children died from asthma (Source Asthma UK (https://www.asthma.org.uk). The market opportunity for the solution is not all children with asthma, but those with severe (5%) and difficult to control asthma (13%). These are segments who have difficulty in breathing almost all of the time and have potentially life threatening asthma attacks that are not controlled by high dose of medication.

Asthma UK state that 2/3's of the these deaths could be avoided.

The technology is also applicable to adult markets (including COPD).

PROJECT SUMMARY

The project focuses on translating Viamed's existing oximeter technology into wearable probes that will facilitate remote monitoring, improve patient safety and also enhance the quality of life, independence and self management of children.

2) Technical Project Summary *

Please give a short assessment of the key technical challenges present in your phase 1 proposal and how these will be overcome. List the key technical deliverables and how they will be met. In addition, please provide a short overview of your SBRI Healthcare phase 2 plans (750 word limit).

Viamed current manufacture and market a variety of oximeters including handheld and finger tip oximeters and a variety of sensors and probes (see attachment 1). The majority of these devices are for the adult market. The technical challenges primary relate to translating existing probes that are designed for fingers or toes into a wearable device that meets the needs of patient and can maintain close interaction with the skin and underlying vascular system during movement. Patient compliance is an addition risk and a challenge that the project needs to overcome. This is the primary reason why the methodology used is to ensure the product design is patient-centric. The product design activities will focus on determining user needs and converting these to design inputs and concept freeze creating a range or prototypes that will be prioritised and validated by presentations to key stakeholders (including patients).

The end point and key output of phase I will be the transfer of the design of the 'wearable probe' for formal prototyping. Phase-II will involve the manufacture of robust prototypes that will be used for clinical evaluation in phase II of the project.

Phase-I will therefore use best practice innovation methodology to translates unmet needs into prioritised measurable elements that are critical to quality (CTQs) and to define design inputs which will be used to design alternative virtual prototypes

Overall aim of phase-I is to produce a product specification for a deliverable prototype probe that will be manufactured and clinically tested during phase II. In parallel a competitor assessment will be continuously conducted to ensure the right to market and also to ensure the product indications and claims are sufficiently differentiated from alternative solutions.

Below a brief summary of the plan is provided

MONTHS 1-2.
- BENCHMARKING OF EXISTING PATHWAYS and devices used by GPs, Yorkshire ambulance service

and home/community monitoring (this will include characterisation to the types of children monitored and length of time monitoring is required)
-SCALE OF THE PROBLEM– collection of data from the ED at SCH to look at the number of inappropriate referrals from GPs (this will further define the problem and help support future adoption).
- COMPETITOR ANALYSIS-Benchmarking of competitors systems and limitations. Using the prioritised needs competitor products will be benchmarked and a deeper IP assessment conducted. This will allow the wearable solution concept to be enriched into a commercially viable concept that can meet unmet clinical needs and also can be strongly differentiated from competitor offerings

DELIVERABLE- Report for each of the above

MONTH 3-4
DESIGN INPUT DEFINITION via a process of prioritisation and segmentation of needs and conversion to critical to quality (CTQs) (that are quantitative and measurable). This will involve initial 1:1 interviews with key end users. The output from this phase will be used to design and execute two focus groups. One will be clinical focussed (GP practices, ambulance service, and community nurses/technicians) and the second will be patient focussed.

DELIVERABLE - report identifying prioritised needs. These will be used to define the design inputs. In addition appropriate clinical outcomes will be defined that will feed into the evidence generation plan for successful adoption (this will feed into phase II).

NHS ETHICS SUBMISSION of documents for ethics approval to facilitate clinical testing during phase II.
DELIVERABLE- Approval before the end of phase-1.

MONTHS 5-6
CONCEPT ENRICHMENT. Using the validated product design inputs from the above alternative designs will be created (i.e. what the device will look like from a wearable perspective along with performance specification).

DELIVERABLE: Document design of prototypes (utilising product design company (e.g. using CAD or other software as appropriate).

CONCEPT SELECTION (MONTH 6)
Using R&D selection tools (e.g. the Pugh matrix) the optimum concepts will be prioritised and then presented to stakeholders during a validation phase. This robust methodology will reduce technical and commercial risk ensuring the prototypes moving forward to clinical testing have the maximum probability of clinical and commercial success.

DELIVERABLE: Selection of final design (soft-prototyping). This design will be selected for clinical evaluation (for phase 2)

PROPOSED PHASE-II ACTIVITIES
1. Product development – deliverable: working prototype
2. Algorithm optimisation using data from clinical work – collection of raw data from clinical home oximetry studies, sleep unit and ward data on children with respiratory illnesses age 0-18 years.
3. Generation/clinical validation on sleep unit to evaluate against the clinical gold standard and at home to test feasibility in intended environment.
4. Regulatory processes – working towards CE marking, building on the existing knowledge of Viamed
5. Patent submissions
6. Clinical evaluation report (for DHF).

3) Key Competitors and Intellectual Property *

Please provide details of any competitor technologies or market alternatives and the relative benefits of the proposed technology that fits the defined area of development. Include details of any other existing IP and its significance to your freedom to operate. (500 word limit)

CURRENT TEST METHODS:

There is no pulse oximeter currently available which can:

a) accurately monitor patients able to ambulate and;
b) which uses bespoke paediatric algorithms to obtain accurate results from neonates and young children of different sizes.

The current gold standard involves ensuring the patient is motionless, attaching a probe to either the finger or ear and taking a reading using one of a number of pulse oximeter devices which are organised into four main categories by the NHS: Fingertip, Handheld, Wrist-worn and Bedside/desktop. None of these oximeters are for use by the patient alone, but instead require interpretation by a clinician.

The Sheffield Children's Hospital uses equipment by 6 different manufacturers in 5 scenarios (General ward, Operating theatre, Sleep Unit, Community care, Helena Home Care team) to monitor perfusion in paediatric patients. The largest cohort here is of patients in the community, and none of these products is adapted for accurate continuous perfusion monitoring in a patient able to ambulate.

There remains a gap in the market for a device which can take accurate readings (free from artefacts) from young children whilst the patient is moving, and which can interpret the data and deliver back to the patient clear indications on when to seek the advice of a medical professional. Such a device would allow these children to live more independently and without the need for the current level of medical care, representing an improvement in overall care provision.

INTELLECTUAL PROPERTY:

Viamed Ltd has operated in the sector since 1977. The company does not hold intellectual property protecting the oximetry hardware, however they incorporate encrypted smart Integrated Circuits into their pulse oximetry sensors which offer commercial protection to stop copy sensors being used in other ways. The processing unit will only recognise the accompanying Viamed sensor and vice versa. The algorithms powering the processing unit are also encrypted, preventing reverse engineering.

The project aims to create intellectual property around new-to-market paediatric algorithms which will be generated through data collection at the Sheffield Children's Hospital Sleep Clinic. A new interface for detecting perfusion will be required to fit ergonomically with the patient. This will also be designed and protected.

There is intellectual property being filed in the area at present in the form of wristband devices (Oxitone Inc. CA2882683 (A1)), however these companies have not commercialised a product nor are the developers focused on creating products for the paediatric market. Other organisations

have attempted to address the issue of filtering out artefacts and background noise to deliver an accurate ambulatory perfusion measurement, but the technology is not proven and they have not commercialised these at present (Apple Inc. WO2015084375 (A1)).

The inventive steps for addressing this unmet clinical need will be in algorithm development and probe design, and we believe with the internal knowledge within Viamed and the expertise at SCH within the sleep clinic, they will be able to address these where other attempts have failed. Probe designs and algorithms will be protected as intellectual property.

4a) Project Plan and Methodology *

Detail the milestones necessary to achieving your technical deliverables, these should describe the critical decision points in the project and the success criteria as measureable or objective outputs. A maximum of 15 milestones can be described in the form below.
Please include at least one milestone that must be completed within the first 3 months of commencement and under 'Resources' identify the individuals / subcontractors required for completion of a milestone.
The date a milestone should be completed must be represented as the number of weeks that will have passed after the Commencement Date. A Gantt chart can be uploaded as a separate document to support these milestones.

	Milestone (15 word limit)	Resources (20 word limit)	Success Criteria (50 word limit)	Milestone Completion Week #
1	Benchmarking of existing pathway	Dr Ruth Kingshott and Prof Heather Elphick	Definition of current best practice. This provides the benchmark that the solution needs to surpass and also determine whether the value proposition should be in line with the technology fitting in with an existing pathway or a new one.	4
		Ruth Kingshott and Heather Elphick to engage end users.	Identification and prioritisation of user needs to convert to design inputs to link into	

2	Focus groups 1,2 and 3	Medilink to lead workshop and questionnaire design (with input from all)	product design. Identification of clinical evidence that will be required to be collected during phase II.	16
3	Competitor analysis and IP assessment	Medilink. An external law firm (HGF) will validate the assessment and manage future IP filings (phase II).	Assessment of freedom to operate and gaps/opportunities to file new IP. The exercise will also identify key threats and potentially opportunities. Clarity on rout to market.	8
4	NHS Ethics approval	Prof Heather Elphick and Dr Ruth Kingshott	Permission to conduct clinical evaluation during phase II.	16
5	Conversion of user needs to design inputs	All. The focus groups will play a key role in defining criteria and using inputs to refine product designs	A report that lists design inputs that are critical to quality (and linked to the end user needs). These design inputs will feed into the definition of the final product design.	16
6	Enrichment of concept	All including the Non Woven Research Institute (who will be contracted to aid in the final design and prototyping stages).	The definition of 3-4 alternative designs and benchmarking with market leader (using Pugh matrix). Success criteria is definition of alternative product designs	20
		Dr Ruth Kingshott	Formal clinical	

7	Clinical study protocol	and Prof Heather Elphick	protocol to be used for clinical evaluation work	24
8	Equipment and NHS ethics approval for benchmark testing of existing devices	Dr Ruth Kingshott and Prof Heather Elphick	Permission to evaluate 10 patients using existing devices.	8
9	Testing existing algorithms and products on 10 patients	Dr Ruth Kingshott and Prof Heather Elphick	It is important to benchmark the suitability of existing algorithms to identify and design the algorithm used in the clinical testing for phase II.	16
10	Selection & validation of concept to move into clinical testing (phase II)		that will be moved forward for clinical testing. A final design spec and detailed product design will be the measure of success.	24
11				
12				
13				
14				
15				

4b) Project Management *

Identify the project management processes that will ensure milestones are achieved, describe key risk and mitigation actions. (500 word limit)

Viamed will focus solely on developing the technical solution. Medilink will therefore act as project manager and ensure that milestones are delivered and that any risks are identified and mitigation action is taken.

Minutes of all meetings will be taken and circulated, and project progress is assessed by the project manager. Any spend will be authorised by Steve Nixon (Director, Viamed Ltd) and a formal

sign off procedure will be followed for all technical, commercial and project documentation. Contractors will be engaged to carry out elements of the work and regular meetings and conference calls will be scheduled with all subcontractors to review progress and plan future work. Formal meetings will be conducted monthly.

Prior to commencement of the project a risk management system will be put in place (see preliminary risk register below) in which all contributors to the project will discuss, identify assess and likely impact. A risk mitigation plan will be generated to address each of the project risks. The risk register detailing the risk, impact and probability of it occurring will be monitored at each monthly team meeting.
The initial risk register (below) will be updated throughout the on going research project. This will ensure that all the risks are taken into consideration as the project develops and that new risks that may arise are identified and allocated a responsible owner.

Attachment 1 page 3 indicates a project Gantt chart reflecting the project plan.

TECHNICAL RISKs
1. Risk: It is possible that the current technology will not have the sensitivity/ specificity robustness to monitor oxygen in a moving child . Mitigation: Viamed currently design and manufacture a range of oxygen monitors and as such existing sensors should have the sensitivity / specificity needed. The technical challenge will be to design a wearable solution that can secure the senor to the child's anatomy. The risk is mitigated by developing a variety of alternative designs that should maintain pressure of the sensor with the skin.
2. Risk: Current algorithms are designed for adults and not optimised for children. Mitigation:This is a central focus of phase 2 that will use clinical data to optimise the software.
3. Risk: Competitor activity. There is a risk competitors will launch a product or file IP that will be a barrier to market. Mitigation. Competitor analysis will be conducted throughout the process. The team will use competitor information to ensure the design circumvents any identify intellectual property and also that the oxygen sensor to be developed is differentiated from other products.
4. Risk: Lack of patients: Mitigation:Clinical engagement (Dr Heather Elphick) and clinical research (Dr Ruth Kingshott) (Sheffield Children's Hospital) are part of the project team. Their expertise will ensure relevant stakeholders are engaged to attend focus groups and through the use of the sleep clinical that patients are available for clinical evaluation.

4c) Key Test of Success *

Please describe an appropriate measure of Phase 1 success. This must be a single question that is specific to your project and formulated so that it can be answered with a yes/no response. (50 word limit)

Has a prototype design been defined that has been validated with end users can be protyped and moved forward to clinical testing during phase 2 of the project.

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5) Commercialisation *

Please give an overview of your commercialisation and business plans - from feasibility to market launch, including an estimate of the resources needed to get there.
Likely considerations when answering this question include how the product is likely to be used, by whom, how it will be paid for and distributed, cost and prices where possible and how these compare to key competitors. (500 word limit)

The first six months Phase 1) is to develop the current idea and to use end user need data and to segment this into quantifiable information that is measurable and can therefore input into product design and define the product specifications. Phase 1 will also benchmark the competitors and define the existing pathway, and to begin the process of identifying the evidence needed for commissioners and decision makers to purchase the device. These element will feed into and be ramped up during phase 2 that will determine the best strategy for market access and also create the value proposition.

Viamed already design, manufacture, market and distribute oximeters and as such there is well defined route to market. The TITCH network are clinical partners in the project and the Y&H AHSN (who funded the original workshop) are supporting the project and will take an active role during phase 2 to promote spread and adaption (see letter of support -attachment 2).

Page 2 of attachment one summarises a) the monitoring opportunity that is the focus of the application; b) representative Viamed products, showing proof of the companies ability to commercialise technologies and c) best practice innovation and commercialisation methodology that shows how the final design will be directly translatable to the needs of the patient.

Phase 2

Phase 2 will involve the manufacture and in vitro validation of the device Phase 2 and the use of clinical data to feed in the to algorithm design. This will involve collection of raw data from clinical home oximetry studies, sleep unit and ward data on children with respiratory illnesses age 0-18 years.

During this period the value proposition and health economic case will be prepared including how the technology might help the NHS meet it's performance. This will also involve an assessment of the likely new patient pathway and an identification of key decision makers the would be need to be target to ensure market success.

The last 6 months of the project will focus on evidence generation/clinical validation on sleep unit to evaluate against the clinical gold standard and at home to test feasibility in intended environment.

Other commercial activities
-Regulatory processes – working towards CE marking, building on the existing knowledge of Viamed. In is anticipated that submissions will be filed before the end of phase 2.

-Submission of IP
-Pricing. Part of the work will be to determine the COGS and conduct a price sensitivity analysis with payers and end users

- Distribution. Viamed already market and distribute medical devices products in Europe and the Middle East. These established distribution networks will be utilised to ensure the success of the project.

Viamed have only once before applied and secured public funding. This was the securement of a smart award during the 1990s. This culminated in a product launch and Viamed still actively sell the product. This demonstrates that Viamed have a track record of successfully utilising public funding.

6) Technical Team and Expertise *

Please include details of key team members, advisors and subcontracting organizations.
Key employees that are yet to be appointed can be included in the below 'Employee' table, however this status should be indicated in the Title, First Name and Surname fields, as these cannot remain blank.

Where collaborators take the form of a company rather than an individual in the 'Advisor or Subcontractor' section, the Title, First Name and Surname fields can remain blank. Expertise provided at no cost can be indicated as such by adding '0' into the Day Rate field.

Employee #1

Title	Mr
First Name	Steve
Surname	Nixon
Role Performed in project (5 word limt)	Technology specialist/ lead applicant
Time allocated to project (expressed as FTE %) (5 word limit)	20% FTE
Day Rate (5 word limit)	£470.77
Relevant Experience (150 word limit)	Involved in bio-medical electronics for 35 years, covering development, production and marketing. In 1997 designed and set up Viamed production of SpO2 sensors. Manufactured original and compatible sensors for sale by Viamed and on behalf of some OEMs. Also involved in the development of advanced motion rejection and low perfusion capability SpO2 technologies, initially in conjunction with Dolphin Medical (SpaceLabs), then latterly with Bluepoint Medical. Since 2008 we have developed hand-held & finger oximeters, and integrated pulse oximetry together with capnography. Currently working on pulse oximetry designs of hand held and desk top units, also offering SpO2 boards for OEM applications. In 1999 won a SMART award for the initial feasibility study of developing a foetal heart simulator. This led to us investing in the production and marketing of a product, which is still sold today. The SMART award assisted us in employing an additional two development engineers.

Additional Employees

2

Employee #2

Title	Mr
First Name	John

Surname	Lamb
Role Performed in project (5 word limit)	Design input for sensor deveopment
Time allocated to project (expressed as FTE %) (5 word limit)	10%
Day Rate (5 word limit)	£470.77
Relevant Experience (150 word limit)	John Lamb is bio-medical engineer and the founder of Viamed. His primary focus has involved oxygen monitoring and development of patient monitoring systems. Before Viamed started to develop and manufacture pulse oximetry sensors here in the UK, John instigated a joint venture production of sensors in the U.S. establishing co-operation with specialist developers of opto-electronics and cabling.

Employee #3

Title	Mr
First Name	Jan-Philip
Surname	Bruening
Role Performed in project (5 word limit)	Study of paediatric software algorithms
Time allocated to project (expressed as FTE %) (5 word limit)	20%
Day Rate (5 word limit)	£184.62
Relevant Experience (150 word limit)	Jan-Philip has a BSc and MSc in Biomedical Engineering which he completed in 2014. Jan-Philip has been working with Viamed for two years now; his role is as project engineer for pulse oximetry development, including the on-going development of adult and neonatal pulse oximetry software algorithms.

Advisor or Subcontractor #1

Title	Prof
First Name	Heather
Surname	Elphick
Company Name	Sheffield Children's Hosoital
Role Performed in project (5 word limit)	Paediatric Respiratory clinical/research expertise
Time allocated to project (expressed as FTE %) (5	

word limit)	20%FTE
Cost, including VAT (5 word limit)	£11,586
Relevant skills/attributes (200 word limit)	Heather Elphick MB ChB MRCP MD is head of the department of respiratory medicine at Sheffield Children's hospital. She was appointed as consultant in Paediatric Respiratory Medicine in 2008. She was awarded her MD on non-invasive respiratory measurements in wheezing children in 1999 from Sheffield University and trained in respiratory medicine at Alder Hey Children's Hospital and Melbourne Children's Hospital, Australia. Her particular clinical interests are in sleep medicine and long-term ventilation. Heather has a strong track record in research and was awarded a Visiting Professorship with Sheffield Hallam University in 2014 in recognition of her collaborative work in research and innovation. She has been awarded NIHR i4i grants for development of the Contactless Portable Respiratory Monitor (CPRM) and for development of custom-made interfaces for children using non-invasive ventilation. She has collaborated on further NIHR funded projects including the PLEASANT asthma trial and has recently received an award from the Health Foundation for development of a city-wide behavioural sleep service in Sheffield.

Additional Subcontractors

4

Advisor or Subcontractor #2

Title	Dr
First Name	Ruth
Surname	Kingshott
Company Name	Sheffield's Childrens Hospital
Role Performed in project (5 word limit)	Expertise in Paediatric physiological measurement
Time allocated to project (expressed as FTE %) (5 word limit)	30%FTE
Cost, including VAT (5 word limit)	£6600
Relevant skills/attributes (200 word limit)	Ruth Kingshott BSc PhD is a clinical scientist specialising in paediatric respiratory and sleep physiology. She has worked in this field for 22 years,

	working in sleep centres in Edinburgh, New Zealand and Sheffield since 2003. Ruth has considerable experience in setting up and analysing children's clinical sleep studies and was instrumental in setting up the sleep unit at Sheffield Children's Hospital. She has worked in research and innovation alongside Prof Elphick providing expertise in measurement and data analysis. Her PhD was correlating nocturnal physiological measures with daytime sleepiness and performance and she has over 28 publications in the field of sleep physiology.

Advisor or Subcontractor #3

Title	Dr
First Name	Patrick
Surname	Trotter
Company Name	Medilink Yorkshire and the Humber ltd
Role Performed in project (5 word limit)	Project manager, product design
Time allocated to project (expressed as FTE %) (5 word limit)	20% (FTE) 26 consultancy-days
Cost, including VAT (5 word limit)	21,684
Relevant skills/attributes (200 word limit)	Patrick Trotter PhD MBA (Techmgmt) is the Innovation andCommercialisation Manager for Medilink Y&H Ltd and has over 20 years in product development and commercialisation of health care technologies including working for Johnson and Johnson, SMEs and ran a consultancy to support medical device companies in the UK, US, Germany and Switzerland. Patrick is an inventor on 17 patent applications (including 10 granted patents) and is an author on 14 scientific and innovation management publications. Patrick has a PhD in Biochemistry and Molecular Biology and previous experience in diagnostic projects. His expertise includes technical evaluations, competitor analysis, unmet needs, conversion to product design and business case preparation. Patrick has expertise has knowledge of identifying unmet needs (via market research) and translating these into inputs for product design. Patrick has also experience in preparing value proposition documents (for clinicians, commissioners, patients and other stakeholders). Medilink has links into a broad network and this will be exploited to

	identify stakeholders that can contribute to the design and evidence required to effectively market the product.

Advisor or Subcontractor #4

Title	Mr
First Name	Tom
Surname	Wright
Company Name	Medilink Yorkshire and the Humber Ltd
Role Performed in project (5 word limit)	Research questionnaire design/ faciltator
Time allocated to project (expressed as FTE %) (5 word limit)	16% (FTE) 20 consultancy days
Cost, including VAT (5 word limit)	13,200
Relevant skills/attributes (200 word limit)	Tom Wright BSc, MA. Tom is the Innovation Officer for Medilink Y&H Ltd. Tom has 5 years' experience working predominantly with SMEs to assess and advise on the commercialisation of innovative products and services in the Healthcare and related technology market sectors. Tom has extensive experience of public grant funding processes and with the preparation of compliant research reports. Tom is experienced in determining the commercial feasibility of medical technologies, and has been successful in supporting product development with bespoke market research to de-risk projects seeking further investment. Knowledge of the commissioning framework for medical technologies, and construction of technology specific value proposition evidence reports will be applied to the project.

Advisor or Subcontractor #5

Title	(No response)
First Name	(No response)
Surname	(No response)
Company Name	NIRI
Role Performed in project (5 word limit)	Technical collaborator
Time allocated to project (expressed as FTE %) (5	

word limit)	2.6% (FTE) 3 consultancy days
Cost, including VAT (5 word limit)	5640
Relevant skills/attributes (5 word limit)	The Non Woven Research Institute (NIRI) are experts in the development of non woven technologies and therefore have knowledge and skills that should be useful in the manufacture of protypes

7a) Application Finances *

A summary of the finances for the contractor and any subcontractors should be provided below. Please indicate line-by-line costs of labour, materials, capital equipment, sub contract, travel & substinence, indirect costs, other, as well providing the total costs including VAT.
In addition please provide a justification for the costs of the project.

	Total Cost (£)
Labour Costs *	£23,160.15
Materials Cost *	£2,472.00
Capital Equipment Costs *	£5,520.00
Sub Contract Costs *	£58.710.00
Travel & Subsistence Costs *	£1,770.00
Indirect Costs (please specify below) *	£870.00
Other Costs (please specify below) *	£816.00
Total Costs (Including VAT) *	£93,318.15

7b) Indirect Costs * (300 word limit)

NHS R&D sponsor costs £600
Medipex (NHS IP support) £270

7c) Other Costs * (250 word limit)

The project is composed of contributors from throughout Yorkshire (Keighley, Sheffield and Leeds). The project will involve regular monthly meetings that will be held sequentially at each contributors' facility. An expense cost of £250 for each individual has been allocated to the project based on expected mileage and a maximum provision of £10 per meal). The total costs for travel and subsistence are 6x£250=£1500.

Incentives for participants attending focus groups 30x£15 = £450

Travel expenses for participants attending focus groups 45p/mile, max 20 miles = £270

Materials costs: £2,472.00. £1,440.00 to cover specialist parts for development of sensor/s, these include silicones, plastics, cabling and opto-electronic components. £1,032.00 is to cover electronics for on-board patient data capture

Tooling costs of £5,520.00 are for soft tooling of potential sensor moulding. We anticipated that this will probably involve tooling for silicone parts.

Moulding of parts and production of sensors: £816.00

7d) Payment Schedule *

Please provide a proposed monthly payment schedule over the next 6 months, all entered amounts must be inclusive of VAT.

	Payment
Month 1 *	£12,425.01
Month 2 *	£13,025.01
Month 3 *	£14.035.00
Month 4 *	£23,587.05
Month 5 *	£15,531.05
Month 6 *	£14,715.05

7e) Justification *

Please provide complete breakdown and justification for the above costs (ALL COSTS SHOULD INCLUDE VAT), including daily rates for staff involved and quotes from subcontractors where applicable. (Please not the assessors are required to judge the application finances, in terms of value for money i.e does the proposed cost for effort and deliverables reflect a fair market price.) (500 word limit)

Viamed: Viamed are the company with the technical expertise of oxygen sensors and the route to market. As Viamed will commercial the technology the company is the lead applicant. However,

due to limited bandwidth and Medilink are subcontract to act as project manager and also to provide the skills and resource need to design and validate design inputs that lead into concept generation / enrichment and selection of de-risked concept for clinical evaluation.

Medilink: The Innovation and Commercialisation team at Medilink will project manage the project and also play the lead role in working with stakeholder to define design inputs, desired product specification(s) and concept generation and selection. The team are highly skilled in the innovation process and off courses on the best practice to innovate and commercialise technologies in the life science /health sector. Both Tom and Patrick regularly author clinical evaluation reports for client companies that are a component of the technical file (irrespective of the regulatory classification). Medilink also have key knowledge of NHS driver that will be used to develop the value proposition to drive adoption of the technology. Medilink will also monitor IP and competitor activity during the duration of the project. Medilink’s knowledge commercialisation and technology development
planning will also be utilised in developing the plans for the second phase.

Sheffield Children's Hospital (SCH)
Professor Heather Elphick is a consultant in Paediatric Respiratory Medicine. Dr Ruth is a clinical scientist specialising in paediatric respiratory and sleep physiology. SCH will provide clinical input, design clinical protocols recruit patients for clinician evaluation and patients and clinicians for concept valisation

Non Woven Research Institute (NIRI): NIRI are world experts in non woven technologies. The proposed solution involves translating Viamed oxygen sensor technologies in a form that is a 'wearable' technology. NIRI are involved during phase I as a technical consultant 9to provide design, technical and manufacturability consultancy) and it is likely that they will become a key partner during phase II of the project.