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NHS PROOF OF CONCEPT PROGRAMME

SMART TECHNOLOGY PROJECT

RESEARCH PROTOCOL

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1. Background and summary

1.1 Background

The "Annual Report of the Chief Medical Officer, 2018 Health 2040 – Better Health Within Reach" draws attention to the need for a change in "the narrow approaches" used when attempting to collect data about groups or populations of people and particularly in NHS patients with multimorbidity. Most policy responses and "medical responses" are approaches designed to change the behaviour of an individual or treat clinical problems, without sufficient regard to the context in which they occur. The social determinants of health are notable by their absence. They need to be included in any medical or policy response (Ref: Office for National Statistics, 2018). Many of the health challenges facing the UK population, including rising levels of obesity, diabetes and poor mental health have multiple causes and consequences. They are both products of, and components in, complex adaptive systems. Early inclusive interventions can better slow the progress of the multiple conditions or help them regress (Ref: Davies SC, 2018).

People with long-term conditions are only seen by their Health Care Professionals (HCPs) about **3.5 hours per annum**. The rest of the time they manage with their own resources. Thus, there is the need to explore whether information on patients' vital signs and behaviours captured by wearables, monitors and other smart technologies, can identify such patients and enable them to be helped at a much earlier stage in the development of their illnesses. We believe this may enable HCPs to intervene at a much earlier stage and prevent the development of illness and associated unplanned admissions to hospital or unplanned use of primary care, mental health care or social care resources.

Meeting the needs of the growing number of people with multiple health conditions will be one of the biggest challenges facing the NHS. In 2006/07, 1 in 10 patients admitted to hospital as an emergency had 5+ long term conditions. In 2015/16, the figure was 1 in 3 patients. The number of people in England with 4+ conditions is predicted to double between 2015 and 2035 [Ref: Kingston A, 2018]. With this, there is a need to manage complex multi-morbid patients better to avoid exacerbations and emergency admissions.

Developing new models of NHS care for those with multiple conditions should be person-centred (i.e. their care should be focused on the needs of the person rather than on the needs of the service) and coordinated across primary, secondary, mental health, community and social care. Such new models of care require technology that can supports patients across various settings.
An innovative partnership between NHS England and the Health Foundation is providing quantitative evaluation to show whether local change initiatives, implemented as part of major NHS programmes, are improving care and efficiency. The NIHR Applied Research Collaborations have signalled multimorbidity as a key challenge to be tackled (Ref: NIHR, 2018).

Understanding how confident patients are about looking after their own health is essential to improve patient outcomes and clinical support. With rising demands on the health service, increasing patient self-care is a key policy focus (Ref: NHS, 2019) that can be facilitated by continuous monitoring with smart technologies. The National Health Service has committed to "give citizens the knowledge, skills and confidence to manage their own health" (Ref NHS England, 2013).

People who are more engaged in their own health tend to report better outcomes (Ref: Foot C, 2014). Interventions that improve participants self-rated confidence in complying with prescriptions and maintaining lifestyle changes have been shown to be effective in a number of long-term conditions. A

substantial proportion of the patient population (25%–50%) has low levels of health confidence (Ref: Hibbard JH, 2008) and this negatively impacts outcomes and experience, and increases use of emergency care. When health confidence is high, patients take more exercise, eat more healthily and avoid risks; people with diabetes report better blood sugar control. Health confidence is positively associated with patient's knowledge (health literacy) and ability to access the care they need (Ref: Wasson JH, 2009). Measures of patient confidence and engagement cover a wide domain (Ref: Coulter A, 2017), including patient-centered care (Ref: Ekman I, 2011), self-care education, patient activation and interactive health communication.

The Health Confidence Score (HCS) is a short broad generic measure for use in quality improvement and impact evaluation of the patients own perception of their health confidence. It covers health literacy and knowledge, ability to self-manage, to obtain help and involvement in shared decisions (Ref: Benson T, 2019). Such a measure could be useful both at the individual level to increase awareness of gaps in an individual's confidence, and at the aggregate level. This could be used in tandem with howRu (Ref: Benson T, 2010) which is more time responsive to change. The aggregate HCS is a meaningful summary measure and corresponds with other measure such as PWS (personal well-being score), health status (howRu) and patient experience (howRwe) in social prescribing.
At the highest level, our proposition to South Lincolnshire builds on work that Philips and Helicon Health are already doing in the UK and abroad. Our overall goals however are very ambitious from the perspectives of supporting, enabling and facilitating a series of changes. Success is the result of perfection, hard work, learning from failure, loyalty, and persistence. The architecture and approach that we have designed to support this programme is born of all the above. Our goal is to implement a system that meets the requirements but has the breadth and depth to scale to meet the greatest challenge as outlined and detailed by the 2018 Chief Medical Officer's report.
We believe that through the management of data collected in a variety of ways, we are increasingly poised to deliver what collaborators at Helicon Health have named "Precision Population Health". This enables personalised detection and protection programs to be designed and implemented with people and for people at scale. For example, this data could be collected from:

- The electronic health and care records
- From sensors in wearables recording vital signs and behavioural factors of activity and sleep
- From sensors for gait and from environmental sensors and location tracking on phones

Through the passive collection opportunities, we are looking at baseline and progression of patient reported mental and physical health status.

1.2 Summary

The source of funding for this study is NHS England. This specific funding was made available to the Proof of Concept (PoC) as a research and development project and provides executive governance via its Proof of Concept Programme Board. South Lincolnshire CCG acts as the Contracting Authority for this project. Philips Healthcare is the Prime Contractor and Helicon Health the subcontractor in the project.

The funding has been used to engage:

- Commercial Partners to deliver the PoC research projects in four areas of England (South Lincolnshire, Northamptonshire, Luton and West Essex)
- Channel 3 Consulting to manage the programme on behalf of NHS England, to assist with local project management where required, and to support NHS England in operationalising the results of the research in the NHS.

Each Commercial Partner was selected via an open and competitive procurement process across the EU, in-line with the requirements of the Public Contract Regulations; this approach and the procurement strategy were approved by NHS England prior to publication.

1.3 Measures in respect of Covid-19

Since the procurement was completed, the Covid-19 pandemic has become a global health threat. The public health threat it represents is the most serious seen in a respiratory virus since the 1918 HINI influenza pandemic. The current measures being taken by the UK Government to interrupt transmission have resulted in a need to adapt the research approach to change the way the research team obtain informed consent from participants and interact with participants and NHS staff throughout the study period. The intended process for obtaining informed consent is clearly described in this document along with other adaptions that were necessary to ensure safe and feasible undertaking of the study. The impact of Covid-19 will not prevent the hypothesis being tested nor will it fundamentally change the study design. The smart devices and the questionnaires will not involve human contact. The smart devices come in form of an app that can be installed from the internet. The questionnaires will be sent and completed by the patient on their smart phone, tablet or desktop. We currently are considering how we can safely use a shared Tablet in a Care home to obtain clinical information on respiratory and heart rate and BP oxygen saturation on several patients. This will involve engaging with the residential and care home staff to develop safe procedures; this will be helped by the knowledge of the Covid-19 status of both patients and staff in terms of blood antibody tests on all the staff and all the patients. We hope also that the use of PPE (Personal Protective Equipment) will be confirmed in each of the relevant homes.

In this PoC, we aim to test the hypothesis that:

"If information about patient behaviour, conditions and events, captured from wearables, monitors and other smart technologies can predict demand for services, then, providing these technologies to patients and using the data generated will enable providers to pre-empt and redirect demand or design new services"

This will be tested by deploying a series of smart technologies with sensor based wearables to study participants to collect their physiological data which will then be analysed.

We confirm that no clinical interventions will be made at a participant level during this PoC study as a result of any data collected. Our research is purely observational and will be based on historic rather than real-time data analysis. We can also confirm that all our participant data will be pseudonymised, deidentified and stored securely.

The device readings are blinded to the participants in order to avoid any feedback of the reading that may influence behaviour and ensure that the study remains non-interventional in their usual care. We will also use software based sensors that use the camera on a smart phone or iPad, and web based questionnaires to collect a richer data pool. We will additionally ingest confidential and pseudonymised Health and Social Care and Environmental data and store it all together in a cloud-based platform purpose-built for healthcare, utilising leading technologies and practices in security and privacy. Data scientists and researchers will perform data analysis and model development within the cloud-based platform using the Philips "Workbench" platform. This provides a collaborative development environment with tools that manage the end-to-end process of analytics, analytics asset creation, deployment and support.

Suitable potential participants will be identified by their GP based on set inclusion and exclusion criteria provided by the research team. Participants will either be living in their own residence, in a residential or nursing care home. Informed consent will then be sought according to the recruitment process described in section 3 of this document.

To find the suitable participants the research team will apply **Diagnostic Stratification Technique** algorithms based on Machine Learning, Neural Networks and Artificial Intelligence (AI) to analyse clinical patterns from de-identified patients. These patients' details will already be stored in the NHS in databases such as Hospital Episode Statistics (HES) which is a data warehouse containing details of:

- All admissions
- Outpatient activity
- A & E attendances
- GP data
- Social Care records

By these means we will find pseudonymised NHS patients who have more than 3 long term conditions (LTC) which will be aligned with the capabilities of data collection of the smart technologies to be used during the study. Using this selection process, the research team aims to identify 700 pseudonymised NHS patients to be approached to participate in the study.

Each participant who consents to take part in the study will be issued with one or more of the smart technologies or sensor-based wearables which will not disturb their day to day activities. The allocation of these technologies is described in subsequent sections of this document. For a period of approximately six months we will record their vital signs and other readings in a secure cloud environment. Our data scientists and researchers will then be able to perform analyses and model development. This will conclude the first phase of the research (Phase 1).

In order to develop use cases, patient pathways and service recommendations, which may be largely based on those data collected, we will work with the CSU to ensure information governance permissions are in place to carry this out (Phase 2). We intend to make assessments of the likely qualitative and economic benefits of the predictive system based on the data collected. These will be tested through data quality evaluation, model selection, training data categorisation, learning algorithm(s), sensitivity and specificity analyses to help determine the confidence of the predictive systems (Ref: Longstaff 2010). The benefits can accrue in several parts of the "services". We will attempt to define the proportions in each.

2. Study Purpose

2.1 Testing the hypothesis

The principal research question is to test the hypothesis:

"If information about patient behaviour, conditions and events, captured from wearables and other smart technologies can predict demand for services, then providing these technologies to patients and using the data generated, will enable providers to pre-empt and redirect demand or design new services."

The hypothesis will be tested by deploying smart technologies with sensor-based wearables, software sensors using the camera on a smart phone or tablet, and web based questionnaires to study data from the participants.

We will further include pseudonymised Health and Social Care and Environmental data and store it together in a cloud-based platform purpose-built for healthcare, utilising leading technologies and practices in security and privacy.

Data scientists and researchers will perform data analysis and model development within the collaborative development environment with tools that manage the end-to-end process of analytics, analytics asset creation, deployment and support.

We will also be testing whether the use of multiple smart technologies of this nature, is acceptable to patients, easy to use and comfortable.

The analytics will seek to understand whether the use of such technologies and the data gathered from them, can indeed provide useful information in predicting adverse healthcare events and therefore inform the transformation of health services to make interventions sooner to achieve better outcomes.

3. Study design

A high-level outline of the research study design is illustrated below in Table A.

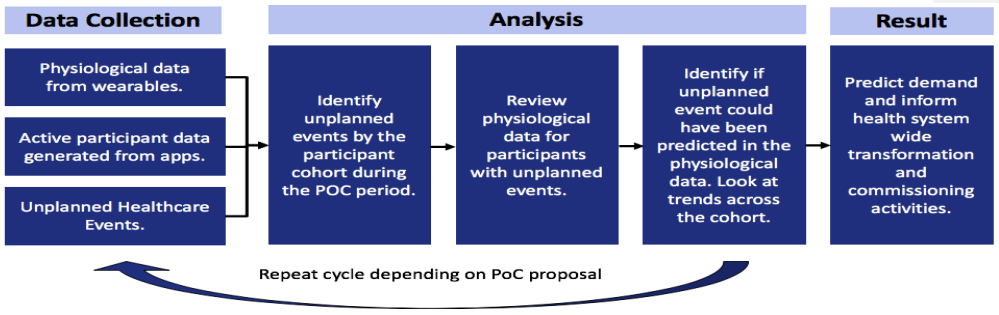


Table A: High Level Outline of Research Design

Our research is observational only and based on historic data. No clinical interventions to a patient's usual care will be made during the study as a result of any data collected. All the data collected will be pseudonymised and will not be monitored or analysed in real time.

The participant will not be able to see the physiological health readings recorded by the smart technologies and so will not have new information about their health which might prompt them to contact their GP or other healthcare services. Therefore, the clinical care of the patient will continue as normal by their GP and/or other health care professionals. This will be fully explained to participants during the recruitment and consenting process.

3.1 Participant eligibility

The research team aim to recruit 500 participants to take part in the study. In order to achieve this target number, the research team aims to identify at least 700 potential participants according to the following inclusion and exclusion criteria.

Inclusion Criteria

- Individuals over the age of 18 that:
  - Have 3 or more long-term conditions AND/OR
  - Have a medium to high frailty score AND/OR
  - Are suffering from unsteadiness or falls AND/OR
  - Those who are found to have paroxysmal and/or asymptomatic atrial fibrillation (AF), hypertension or heart failure
  - Live in their own homes or in residential care homes or in nursing care homes

Exclusion criteria

- Children
- Individuals for whom consent cannot be obtained (i.e. individuals with severe mental impairments or learning difficulties)
- Patients on palliative care
- Individuals lacking mental health capacity or whose mental health conditions might be influenced by participating in the study?
- Individuals who's mental capacity deteriorates during the study period will be removed from the study.

3.2 Participant selection

3.2.1 Participants living in their own homes

The research team will work with the CCG and Commissioning Support Unit (CSU) to identify suitable patients to be approached to take part in the study from pseudonymised NHS patient data.

This will involve using data analysis algorithms called the Diagnostic Stratification Technique, which has been developed by Helicon and their partner i5Health. It is based on Machine Learning, Neural Networks and Artificial Intelligence to analyse millions of clinical patterns from de-identified patient data collected by the NHS in the Hospital Episode Statistics (HES) database. HES comes from data collected by NHS Digital to provide CCGs and care providers with important information pertaining to commissioning and payment for care delivered to patients. However, it is also possible to use this data for research purposes and other secondary uses. This is because strict statistical disclosure control is applied in accordance with the NHS Digital protocol, which suppresses small numbers to stop individuals being identified from the data and ensure patient confidentiality is maintained.

The CCG will formally request Helicon and i5Health to undertake a search for their HES data to produce a list of pseudonymised patients. This list will then be passed to the CSU Data Services for Commissioning Regional Offices (DSCRO) for re-identification. This will ensure that all Information

Governance (IG) requirements are strictly applied. Once re-identification is complete, the CSU will be able to group patients into lists according to their registered GP practice. These lists will then be securely distributed (using NHS mail or other secure connection) to the relevant GP practices so that the participant recruitment process can begin. It is important to note that no party other than the CSU and GP practice will be able view the identifiable patient data at any point prior to formal consent being obtained from the patient directly.

Once each GP practice has a list of potential participants, GPs or healthcare professions will be able to review each patient record individually in line with the study's inclusion / exclusion criteria to make further exclusions where appropriate.

3.2.2 Participants in residential care homes & nursing homes

During preliminary engagement activities, the CCGs Clinical Lead Dr Majid Akram will socialise the study with residential care homes and nursing homes in the South Lincolnshire geography to gauge their appetite take part in the study and become research sites.

Those that agree to take part will be given the studies inclusion and exclusion criteria to select suitable residents who could potentially become study participants. It is very likely that residents chosen to take part by care home professionals will be included on the patient lists given to GPs above; this will be checked once formal consent has been obtained from residents.

It is anticipated that only about a third of participants will be recruited from care homes or fewer if engagement activities prove it is impractical.

3.3 Participant recruitment and consent

3.3.1 Recruitment of participants living in their own homes

The study intends to recruit 500 participants to take part in the study and will therefore aim to invite at least 700 to individuals to participate.

To do this, the research team will provide GP practices with the following participant facing documents to use in recruitment activities with their own patients:

1. **Participant Invitation Letter**
   This will give a brief summary of the study and instructions on how to either accept or decline the invitation.
2. **Participant Information Sheet (PIS)**
   This will provide a more detailed explanation of the study including what the participant will need to do, why we are undertaking the study, how they can withdraw from participation etc. a copy of the PIS has been submitted with this application.
3. **Study Consent Form**
   This will be the formal consent form that participants will sign to agree to take part in the study. Due to Covid-19, consenting processes have been adapted to ensure that consent is undertaken remotely. The Clinical Research Network have confirmed that the consent form can be posted to participants as part of the initial communication. Prior to Covid-19, consent would have been obtained in a face to face meeting with a healthcare professional. Please see section 3.3.2 below for full details).

4. **Text Message Content**
   A follow up text message will be sent to those potential participants who have a mobile number recorded with their GP practice. It will refer them to the study pack sent in the post and include a link to the cloud environment where they can securely complete their consent form online.

The GP practice will send the information pack above to each potential participant and include a prepaid return envelope addressed to Optima Systems Ltd for them to return their signed consent forms. The invitation letter will also include a URL where participants can complete their consent form electronically online if they prefer. Optima Systems Ltd will collate and store signed consent forms for a period of XXXXXX

Commented [CP2]: I think we say indefinitely elsewhere in the documentation although I'm not sure if this is acceptable – other studies are destroying them some time after the study ends.

The participant will be given three options:

1. Sign and return the consent form if they are happy to take part (either online or by post)
2. Do nothing if they do not wish to take part – it will be assumed that they do not want to take part if a consent form is not received within 2 weeks
3. Call Clinical Research Network for more information and/or to complete consent form over the phone

Potential participants are asked to complete consent forms withing one week if they would like to take part. If nothing is received after 2 weeks, they will be removed from the study invite lists by GP practices.

3.3.2 Consent of participants living in their own homes

The participant invitation letter will advise potential participants that if they are happy to take part in the study and do not require any further information, they can sign the enclosed consent form and return it in the envelope provided or they can visit the study website to complete the consent form online.

The invitation letter will also advise that if they would like more information or are not able to return the consent form by post, they can call the Clinical Research Network to discuss further and have their consent taken over the telephone. This will provide participants with the opportunity to ask questions before deciding. The CRN have agreed to support this activity. However, if for capacity reasons they are not able to provide resource to do this at the time recruitment begins, GP practices will be asked to support this activity instead and the Participant Invitation Letter / PIS will be updated accordingly before being sent out.

The participant consent form has been submitted as part of this application and will ask the participant to consent that they:

- have read and understood all the information about the study and have had all your questions answered satisfactorily
- taking part is voluntary and you can stop taking part at any time without this affecting your medical care or legal rights in anyway
- understand we will not intervene in your usual care while you are taking part in the study
- members of the Research Team will read relevant sections of your medical history and that you give permission for the Research Team to access this information
- understand that the information collected about you will be used to support other research in the future and may be shared anonymously with other researchers

- agree for your GP to be involved in this study and that necessary information about you will be exchanged between your GP and the Research Team
- understand the information held by the researchers may be used to contact you but only while you are taking part in the study
- agree to take part in the study and undertake the required study activities (i.e. take your own health readings and/or wear a comfortable Smart Device over the period of the study which will securely record data about your health)
- are happy for your data to be collected, used, shared and stored as described in this information sheet
- understand you will not gain any particular benefit from taking part, but may be helping others in the future

Consent forms will be returned by post to Optima Systems. Optima Systems are responsible for generating the unique ID number for you for the purposes of the research. This ensures that all the data collected from participants will be pseudonymised.

Optima Systems will call the participant upon receipt of their consent forms to check all the information provided is correct and undertake a technical assessment to establish which equipment needs to be sent to the participant. Although device will be allocated at random, the research team will need to understand the connectivity and infrastructure available.

Optima Systems will then inform the participants GP that they have been onboarded to the study and ask the GP practice to cross check the information collated on the consent form to ensure that only invited participants are included. This will also help GP practices manage recruitment lists and remove anyone who has not consented from the study and any future recruitment rounds.

3.3.3 Recruitment in residential care homes & nursing Homes

The care home manger / care home professionals will be responsible for recruiting and consenting their residents. No one from outside the resident's usual care team will visit the care home before or during the study.
After initial selection is completed as described above, care home professionals will speak to suitable residents to gauge their interest in taking part and provide them with the following study literature:

- Participant Invitation Letter (as above tailored to study processes within a care home setting)
- Participant Information Sheet (as above tailored to study processes within a care home setting)

Residents will then be given as much time as they need to consider taking part in the study; they will also be encouraged to discuss the study with friends or relatives. They will be asked to notify their care home manager or usual care home professional if they decide they are happy to participate.

3.3.4 Consent of participants living in residential or nursing care homes

Care home professionals will also be responsible for obtaining informed consent from its residents. Once a resident has expressed verbal interest in taking part in the study, the care home manager or care professional will meet with them to complete the consent form and provide further opportunity for residents to ask questions.

The consent form will be signed by both the resident and the person taking consent and a copy of the sign consent form will be given to the participant.

The details of consented participants will then be passed to Optima Systems. Optima systems will liaise directly with the care home manager / staff in order to provide equipment and onboard participants to the study.

The participants will be advised that we are not using face-to-face methods and pamphlets as a Covid-19 precaution. Instead we will use what we are calling "participant facing documents" to explain the study and will be encouraging questions, with the intent of ensuring that participants are fully informed in some detail.

3.4 Participant onboarding

3.4.1 Allocation of devices

Once participants have provided their consent, each will receive a phone call from Optima Systems Ltd to:

- Ensure the information provided is correct
- Check that the participant is still happy to proceed
- Reiterate the key points of information provided in the Participant Information Sheet
- Establish the current technical capability of each participant i.e. WiFi connectivity

We intend to choose the most suitable smart technology for each patient. The choice of the smart technology is based on careful judgement and we will aim to develop an approximate "right app or wearable for the right patient" as clearly as we can. We will do this based on the initial conversation held with the participant.

Since patients do not necessarily become ill with the same conditions they already have, one or at most two devices per patient will be chosen. We are aiming to include about a third of the patients from residential and care homes since they will tend to be more vulnerable and more likely to have an adverse health event and certain apps can be used by smart devices can be installed from the internet.

The questionnaires will be sent and completed by the patient on the smart phone, tablet or desktop. We currently are considering how we can safely use the same tablet in a Care home to obtain clinical information on respiratory and heart rate and BP oxygen saturation on several patients. This will involve engaging with the residential and care home staff to develop safe procedures; this will be helped by the knowledge of the Covid-19 status of both patients and staff in terms of blood antibody tests on all the staff and all the patients. We hope also that the availability of PPE (Personal Protective Equipment) will be confirmed in each of the relevant homes.

The next action will be to arrange for the participants to receive the wearable or smart technology and to be shown how to use it by the "research supporter" with the aid of the internet. We will be allocating participants randomly according to their circumstances, to receive two (or at most three) wearables or smart technologies.

Commented [CP3]: Updated slightly as we have concluded device allocation will be random to an extent – please ensure my wording is accurate here

Commented [CP4]: I think we should go further here and propose a process otherwise it is quite a big question mark – this will link back to the SOP you are developing Tony.

Commented [CP5]: Can we say – "Optima will then post devices and instructions on how to use them to participants. As soon as the participant receives their devices they will be able to start using them to take health measurements straight away. If a participant has any difficulty in using their devices, they will be able to call Optima Systems for support and guidance".
This is what we have said in the PIS.

Device / App name	Physiological measurement	Characteristics of device / app	Participants
LifeLight	• Respiratory & heart rate, BP & pO_2	Digital camera on iPad	As many as possible – proportion shared in Care homes – **readings daily**
Thermometer	• Temperature	Hand held thermometer	All participants for **6 days/week**
FibriCheck	• ECG – (FIBRICHECK)	Visual Plethysmography	300 participants – **daily readings**

Device / App name	Behavioural measurements	
GENEactive Band	• Activity intensity / duration & frequency/ sleep quality	500 participants **Daily readings**
QuestLink	• Mental, social and physical health status and progression. Measures of patient self-confidence (HCS) and Health Status (howRU)	All participants -**on average twice weekly**

Commented [CP6]: Have removed two paragraphs here that talked about "Phase 2"

3.4.2 Participant training

The first action will be to ensure that the participant understands that during the study we want to keep life as normal as possible for them. There will be no new drugs being tested, no special behaviours asked of them, and no medical tests to be done and no additional consultations needed.

We will be just recording data and collecting it from your wearable or smart technology supplied to them. Participants healthcare will carry on as usual with their GP and healthcare professionals and the medications that they are taking will be managed as normal by them.

The second action will be to arrange for the participant to receive the wearable or smart technology and to be shown how to use it by their "research supporter". We will be allocating participants randomly according to their circumstances, to receive two (or at most three) wearables or smart technologies. Education in its use will also be started and this will also explore how we can minimise any inconvenience for you. Pamphlets and other information will be given to the participant as well as contact numbers. Depending on the IT connectivity at home it may rarely be necessary to make arrangements to meet to participant to download the stored data on the wearable or smart technology. The participant will be well supported with support on offer during the trial by messaging electronically, or by phone and speaking to one of our helpers.

Commented [CP7]: Tony, can we discuss this paragraph – may need some rewrite

3.4.3 Ongoing participant support

The participants will be supported for the trial by phone or email and speaking to one of our support staff at Optima. The support staff will also identify problems if there were a change in data flow from the devices from the participant, and seek to resolve them.

4. Smart Technologies

Each participant will be issued with one or more smart technology which will not disturb their day to day activities over the period of the study; during this period of time they will receive uninterrupted health care.

To gather meaningful information within the budget and time available, we need as large a sample size as possible which will also minimise the costs [of wearables]; it will facilitate the eventual solution economically scaling up to meet the rapidly growing and aging population. To meet the potential for scale, we will use a smart technology solution that is scalable and collects data from participants as passively and non-invasively as possible. This can involve looking at the camera on a tablet computer for thirty seconds or placing a finger over the camera on a smart phone for thirty seconds twice daily over the period of the programme. These smart technologies generate large volumes of raw data which will be pre-processed to identify discrete events or clinically meaningful and relevant measures.

The choice of the apps and wearables for an individual participant is carefully judged. We aim to achieve the "right app or wearable for the right patient" as accurately as we can. Since patients do not necessarily become ill with the same conditions they already have, apps may be chosen that do not relate to existing conditions. We will choose about a third of our participants from those who reside in a nursing care home and residential homes since they will tend to be sicker and more likely to have "an event" that may become predictable with the data collected. And also because some of our chosen apps can be used on more than one participant in a care home setting, this will provide coverage of participants with apps.

We believe the above approach to proven smart technologies will enable:

{i} **Detection** - of risk factors or undiagnosed conditions
{ii} **Protection -** from long term conditions by mitigation of risk through various interventions including social prescribing
{iii} C**orrection of conditions -** many physical and chronic conditions are either reversible or the progress of the condition can be slowed

4.1 Our chosen wearables, sensors and monitors

The core of our chosen solutions are highly innovative and include the following:

LifeLight from XIM is a contactless solution and is certified for the Apple iPad with a built-in camera and a smart phone with IoS or Android with a camera. The iPad based smart technology (LifeLight from XIM) allows measurement of four vital signs (heart rate, blood pressure, oxygen saturations and respiration) in just 30 seconds using a standard Apple iPad, with no additional hardware. Lifelight® is a software application (app) which allows completely non-invasive and non-contact measurements. It has satisfied the essential requirements of the Medical Device Directive (94/42/EEC) for CE marking.

FibriCheck from Qompium will be used to measure ECG and to detect heart irregularities, as this is the only medical grade CE certified (class IIa) application to detect cardiac arrythmias using only a smartphone with no additional hardware or device. FibriCheck has been validated in several clinical studies compared to the gold standard 12 lead ECG. FibriCheck has a similar diagnostic accuracy compared to Alivecor single-lead ECG. FibriCheck is certified as a Class IIa product and is Certified under Directive 93/42/EEC and all software is compliant to ISO62304 – Medical device software. Other applicable standards include : EN ISO 980:2008 Symbols for use in the labelling of medical devices; EN 1041:2008 Information supplied by the manufacturer of medical devices and Good clinical practice (ISO 14155:2011).

GENEactive Band produces raw data real time with real time output. A further aspect of our hypothesis calls for the measurement of activity and quality of sleep, as life-style is one the most important factors in the prevention, treatment, and management of many long-term conditions. Since 2008 Activinsights have used lifestyle insights from wearables and connected devices to digitally support healthcare services in over 40 countries around the world. Active insights technologies and data analysis approaches are supported by over 300 peer-reviewed scientific papers. Products are made in the UK to ISO 13485. The GENEactive band is not a Medical Device and is not currently registered with MHRA. In view of the changed regulations in 2020 the Activeinsights registration is in the process of being developed.

QuestLink enables surveys to be automatically scheduled and distributed to the participants devices. This will include measures of participants self-confidence (Health Confidence Score) and Health Status (howRU) for participants with multimorbidity; mental health, social and physical health status, and progression; current medication and changes and others. It will also include the use of a handheld thermometer to enter the temperature 6 times a week.

TABLE B – Measurement details, devices and details of device/app

Physiological measurement	Device / App name	Characteristics of device / app
• Respiratory rate	LifeLight	Digital camera on iPad
• Oxygen saturation	LifeLight	Digital camera on iPad
• Blood pressure	LifeLight	Digital camera on iPad
• Temperature	Thermometer	Hand held thermometer
• ECG – (FIBRICHECK)	FibriCheck	Visual Plethysmography

Behavioural measurements	Device / App name	Characteristics of device / app
• Activity intensity / duration & frequency	ActivInsights Band	Wearable Band
• Sleep / Circadian cycle / Sleep time and duration & quality	ActivInsights Band	Wearable Band
• Acceleration monitor for bone health	ActivInsights Band	Wearable Band

• Rehabilitation balance and safety in falls patients	ActivInsights Band	Wearable Band
• Mental, social and physical health status and progression. Measures of patient self-confidence (HCS) and Health Status (howRU)	QuestLink	Cloud based Response to questions – personalised and automatically scheduled and distributed to participant devices

Environmental & Social determinants of health		
Air quality - pollutants	Sensor Related to postal code	Static – accessed from "public sites"
Postcode or GP Postcode –	First digits of postcode	Static data
Lincolnshire Research Observatory (LRO)	Index of Multiple Deprivation (IMD)	Static – accessed from "public sites"

4.2 Pseudonymised data content

At the end of the pseudonymised data collection phase, we will have drawn from 4 main sources for each participant:

a. **Pseudonymised data drawn from wearables, sensors, devices and monitors**
b. **Pseudonymised related data drawn from several NHS sources**
c. **Geographically related data drawn from environmental sources (MetOffice, DEFRA)**
d. **Pseudonymised participant (with multiple morbidities) related questionnaire results including participant outcome measures**

Pseudonymised data drawn from wearables, sensors, devices and monitors – individual participant specific (anonymised) data which will include: See table B above.

a. **Pseudonymised patient data drawn from NHS including:**
   - GP or HCP attendances (or visits) in the period of study and would include reason for attendance
   - NHS Hospital Episode Statistics (HES) data for South Lincolnshire, containing details of all admissions, outpatient diagnoses and A & E attendances, together with GP data records for the whole patient group for the 2 years preceding the study together with the study period and one year into the future to evaluate impact.
   - Known procedures (OPCS, SNOMED CT, etc.)
   - Prescribed drugs and changes in the period of the study (and make this for 2 year preceding the study and one year into the future).
   - GP Data and Social Prescribing Data.
   - Post code or postcode sector of patients to facilitate linkage to the deprivation index (IMD) and environmental data.
   - Death or other severe events

b. Data drawn from environmental sources will include:

- Air quality and weather – pollutant levels e.g. temperature, dew point, etc.
- Postal sector of pseudonymised patients

c. QuestLink questionnaires at intervals including:

- HowRu and Health Confidence Score (HCS) – Person Reported Measures of Outcomes
- Questions about events in the family
- Medication related questions including use of "over the counter medications"
- Activity levels

4.3 Clinical Event Grouping

To anticipate an illness is a clinical challenge. In many instances a future illness bears no relationship to the conditions the patient already has. There is evidence that patients presenting with a heart attack actually visited their GP with non-specific symptoms in the days prior to the onset of the heart attack symptoms. We aim to explore whether the likely "unplanned events" which are *clinically orientated*, that will "trigger further investigation and/or treatment" can be categorised; and subsequently explore whether the actual clinical event *might have been prevented* by acting on the "data signals"; these might arise from changes in the patient's behaviour, their physiology or their behaviour, or from the environmental or social determinants of health data. Table C below classifies the "type of clinical event" in the left column; the process that might have caused it in the middle column; and the clinical diagnosis that might be made in the right column. There will be a lot of overlap between the columns, but it may help relate different forms of classification to one another – the physiological and behavioural; the clinical; and the environmental and the social determinants of health.

Clinical Event (& Timing)	Type	Reasons for illness
Outpatient visit	New or Old (Follow-up)	What conditions?
Acute In-patient stay (days)	Acute/Hospice/Palliative/Mental health/	Day ward assessment
		Ambulatory ward assessment
Infections	Upper and lower respiratory/chest/asthma/COPD /Gut/Sepsis/Flu/pneumonia/ENT /Cellulitis/Covid-19	Respiratory/Sepsis/Infection/Malignancy
Cardiovascular system	Heart attack/AF or PAF/Venous thrombosis/Stroke/TIA/Palpitation/Heart failure/Angina	Heart failure/ heart attack/rhythm
Psychological events	Stress/dementia/confusion/Sleep issues/Smoking and drug habits/Activity levels/recent bereavement/Acute crisis	Alcohol, confusion, neuropathy/Mental
Falls or unsteadiness	Trip/Fracture/head injury/Off legs	Musculoskeletal/ Frailty
Social deprivation related	Multimorbidity cluster/new composite Health Index Air quality and weather related respiratory exacerbation	

		Captures many social determinants of the population's health (postal code in UK; income category etc etc)

Table C – High Level Attempt to Classify Clinical Event with Type of Event and Possible Reason

5. Data flows and management

Our Digital Platform is a cloud-based platform purpose-built for healthcare utilising leading technologies and practices in security and privacy. Our proposed concept solution is based on collecting participant data using sensor based wearables, software based sensors using the camera on a smart phone or iPad and web-based questionnaires. This data is then ingested and stored, together with NHS activity data.

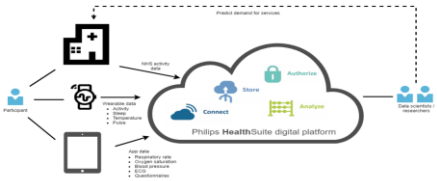
Data scientists and researchers will be able to perform their data analysis and model development using the cloud based platforms Workbench. This provides a collaborative development environment with tools like RStudio or Jupyter Notebooks using technologies like TensorFlow or PyTorch and visualisation tools like Tableau or MS BI Studio and manages the end-to-end process of analytics, analytics asset creation, deployment and support.

The cloud based platform is certified for ISO27001 (information security management system) and ISO27018 (protection of personally identifiable information (PII) in public clouds acting as PII processors). ISO27018 certification is a means to demonstrate EU GDPR compliance.

For the PoC, our commercial partner, Philips commits to:

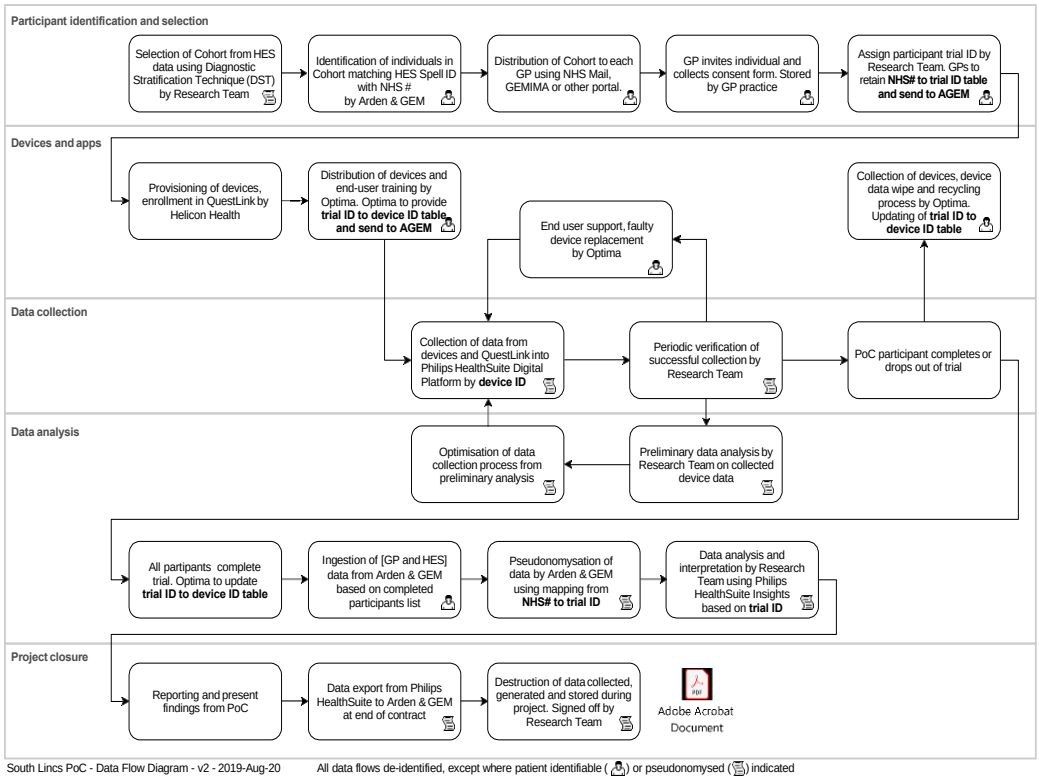
- act as the Data Processor as defined in the EU General Data Protection Regulation (GDPR) and only process data as agreed with the Authority.
- use the relevant information standards as published by the Department of Health or NHS England for data collection, transfer, storage, processing & destruction throughout the PoC
- comply with Code of Practice on Confidential Information for data collection, transfer, storage, processing & destruction throughout the PoC
- leverage our extensive experience in interoperability, we will transmit and persist data using open interoperability standards where possible.
- use our global experience as a manufacturer of medical devices, certification to ISO13485 to ensure safe data collection, transfer, storage, processing & Logging service: provides centralised log management for collecting, analysing and displaying logs for cloud-native applications to analyse performance or bugs.
- providing Identity and Access Management (IAM); this is a secure, centralised mechanism to manage identities, authentication and authorisation of users, service and devices and enable access control. It includes Terms and Conditions Management to manage consent and ensure data security and privacy.

Solution



Our proposed solution is based on collecting participant data in an easy to use and scalable way through sensor based wearables, software based sensors using the camera on a smart phone or iPad and web-based questionnaires. This data is then ingested and stored, together with NHS activity data, into the Philips HealthSuite digital platform (HSDP), a cloud-based platform purpose-built for healthcare utilising leading technologies and practices in security and privacy. Data scientist and researchers will be able to perform their data analysis and model development within the HSDP using the HealthSuite Insights Workbench. This provides a collaborative development environment with tools like RStudio, Jupyter Notebooks and TensorFlow and manages the end-to-end process of analytics asset creation, deployment and support.

Table D: DATA FLOWS



South Lincs PoC - Data Flow Diagram - v2 - 2019-Aug-20 All data flows de-identified, except where patient identifiable ( ) or pseudonomysed ( ) indicated

Data Tables for Consent, Device Distribution and Research

NHS# to Trial ID
Held by GPs and AGEM

NHS#	Trial ID	Patient Details

Trial ID to Device ID Distribution
Held by Optima and AGEM

Trial ID	Device ID	Patient Details	Distribution Status

Trial ID to Device ID Research
Held by Research Team and AGEM

Trial ID	Device ID	Distribution Status	Device Data

Note that fields in RED are IG sensitive and should be held by GPs and Optima during device distribution and send to AGEM after distribution is completed. The tables "NHS# to Trial ID" and "Trial ID to Device ID Distribution" are used at the later stages at AGEM to enable inclusion of GP data and HES data.

Table E - Data flows and Data table for Content, Device Distribution and Research

5.1 Data Collection

5.1.1 Application of the i5 Diagnostic Stratification system

Helicon and its partner i5 Health will be applying the i5 Diagnostic Stratification system (i5 DST) – which uses algorithms based on Machine Learning, Neural Networks and Artificial Intelligence (AI) to analyse millions of clinical patterns from medical records to identify the most suitable cohort for this programme. More specifically, i5 DST is an algorithm-based Artificial Intelligence clinical evaluation tool that can identify undiagnosed patients with a high likelihood of having an undiagnosed Long Term Condition (LTC). It uses pseudonymised patient medical history and estimates the probability of the patient having or developing, an LTC. DST facilitates proactive patient management that delivers patient-centric care to reduce unscheduled admissions by targeting two groups of patients i.e. those with:

- High Probability of currently having an undiagnosed LTC
- Potential of developing an LTC in the near future

5.1.2 Testing prior to commencement of Proof of Concept Study

In the weeks preceding the commencement of the study the following will be performed on healthy consented volunteers and checked for:

- Data flows and quality from person to sensor/app/wearables and then to data store
- Identification of databases with air quality sensors and temperature measurements
- Data flow to check with expected normal measure and also with unexpected measure to facilitate the appropriate responses of their devices to detect an "event"

5.1.3 The start of the PoC Study

The start of the PoC study will, in the first 2-3 weeks, entail the recording physiological and behavioural data on pseudonymised participants and will serve to calibrate the expected measurements of each individual participant. Once the formal cohorts have been created and the individuals are supplied with and using the appropriate equipment, data scientists from Helicon and i5 Health will use the unique research platform with six months of sensor based data. During data analysis and model development, various hypotheses will be tested against the data.

The use of QuestLink, an electronic questionnaire will enable us to collect mental, social and physical health status and its progression on individual participants on a regular basis. It can also serve as a messaging service to collect such information from the participants as a list of their current medication, wellbeing or their minor illnesses. It will enable the use of measures, relevant to patients with multimorbidity, of patient self-confidence (HCS) and Health Status (howRU).

5.2 Data analysis

The use of Artificial Intelligence (AI) is being increasingly used as predictive healthcare solutions to provide early detection of long term conditions that anticipate and can thereby prevent illness and disease. One such common example of this technology used for screening is Atrial Fibrillation (AF) which utilises Artificial Intelligence techniques such as Principal Component Analysis (PCA) and Neural Networks (NN) (Ref Braun 2018). Artificial Neural Networks (ANNs) provide a powerful technique for modelling complex non-linear relationships for classification. Neural Networks are commonly applied in non-linear predictions to analyse the complex relationships and correlation that exist between patient history including the social determinants of health, and development of future conditions, and also between the physiological and behavioural measurements.

The NHS has the great advantage of having vast amounts of historic patient data in standardized form suitable for analysis and AI training. The Healthcare industry is data-rich, but it is not always possible to extract the required information from the data in a timely manner or in a manner that is useful to the patient or healthcare professional.

As a separate part of the study (phase 2) we intend to make assessments of the likely qualitative and economic benefits of the predictive system based on the data collected. These will be tested through data quality evaluation, model selection, training data categorisation, leaning algorithm(s), sensitivity and specificity analyses to help determine the confidence of the predictive systems (Ref: Longstaff 2010). The benefits can accrue in several parts of the “services”. We will attempt to define the proportions in each.

Benefits will accrue to the patient, the family and work; they will also accrue to the health and social services when the specific event or illness is avoided. We will study trends across the cohort that were part of the PoC (patient participation groups PPG) compared with a similar cohort of patients that were not part of the PoC (patients reference group PRG) and report on the findings.

The design of the input data set requires the size of the data set to be defined. A larger data set will require more time to train the machine learning algorithms. The balance between learning capability and learning time will be considered and set with outcome requirements. The methodologies for the clinical components are based on existing implementations of Neural Networks for preliminary diagnosis to support targeted screening in the NHS.

Developing of machine learning algorithms can be split broadly into five stages.

a) Obtain data that is pseudonymised and consists of a representative cross-section of patients with and without the condition or an adverse event

b) Reduce the number of feature parameters that are relevant using de-correlation methods such as Primary Component Analysis (PCA)

c) Split the data for machine learning training, monitoring of overfitting and performance testing to facilitate evaluation of prediction quality and applicability

d) Train various machine learning models and topologies to evaluate which combination works best for the required predictions

e) At the end of the study, device data will be connected to primary and secondary care data to build full medical records of participating patients. Such longitudinal medical records facilitate the prediction of future events to deliver pro-active care.

Joining the Device Data with GP and Hospital data requires a consistent key across all three data sets. Depending on the data structures held at Arden and Gem (AGEM) CSU, the Trial IDs can be mapped to a clear either to clear or pseudonymised NHS number, with a preference for pseudonymised NHS numbers.

GP and Hospital data extraction will be performed by applying the list of participating patients as a filter. This filter will be the list of pseudonymised NHS number where possible.
The resulting data structure will be a collection of clinical and non-clinical data sets that can be linked via a pseudonymised primary key, or NHS number, location and calendar date for air pollution or weather data. **See table E – above**

5.3 Results and Project closure (see Table D: Data flows)

The CCG's commercial cloud-based platform (Philips Healthsuite) purpose-built for health, will collect participant data in an easy and scalable way through sensor based wearables, software based sensors using the camera on a smart phone or tablets and web based questionnaires. The data will be ingested and stored. Data scientists and researchers will be able to perform their data analysis and model development within the secure cloud based platform using the Workbench. This provides a collaborative development environment with tools like RStudio, Jupyter Notebooks and TensorFlow and manages the end-to-end process of analytics, analytics asset creation, deployment and support. It will comply with the Code of Practice on Confidential Information for data collection, transfer, storage, processing & destruction throughout the PoC.

We are already having informal discussions with the Data Access Request Services (DARS). Once we have received approval for the study we will complete our application to them together with consideration of the GPES data for pandemic data.

The data will be securely stored by Arden and Gem CSU at the completion of the study.

5.4 Study Steering Group

A Study Steering (SSG) will oversee the organisation, the data quality and the output of the study. The steering group will oversee the data flows and management. To aid them they will use make use

of a monitoring device that ensures the correct and consistent correlation of the participant's PoC study number with the ID number of the wearable, sensor and monitor; and will generate a warning of any inconsistency.

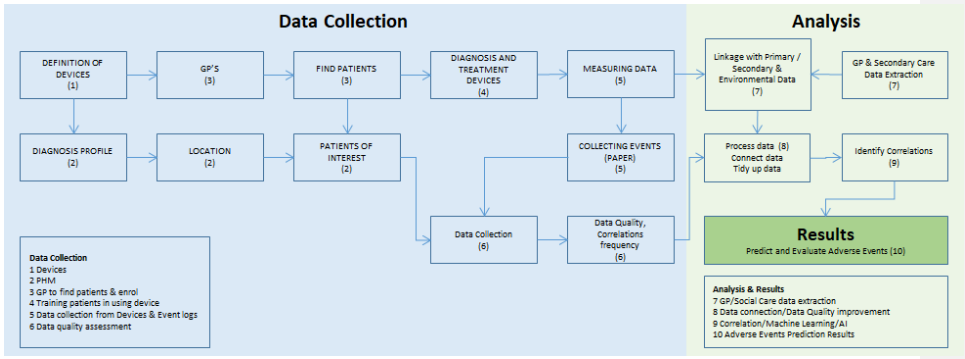
Table F below illustrates the flow of data in the analytic phases of the PoC Smart Technology Data Study Trial:

Phase 1 with the flow from the physiological and behavioural data mainly but with QuestLink data also

- Phase 2 with the additional data from the clinical health and social care data, together with Air quality
- Predict events Phase 1 with the "predict events" data
- Budget Phase 1 with the budget data linked to the relevant phases and support the development of the transformation report

Commented [CP8]: Needs rewording to fit with new study stages
Data Collection
Analysis
Results

Table F: FLOW OF DATA PHASING DIAGRAM IN PROOF OF CONCEPT STUDY



6. Ethical Considerations

Due to Covid-19, consenting processes have been adapted to ensure that consent is undertaken remotely. We considered adopting electronic means but have now decided to adopt a modified paper based system which has produced good results and with which the LCRN are familiar.

The research team will provide GP Practices with the following "participant facing documents" to use in recruitment activities with their own patients:

1. **Participant Invitation Letter**

This will give a brief summary of the study and instructions on how to either accept or decline the invitation.

2. **Participant Information Sheet (PIS)**

   This will provide a more detailed explanation of the study including what the participant will need to do, why we are undertaking the study, how they can withdraw from participation etc. a copy of the PIS has been submitted with this application.

3. **Study Consent Form**

   This will be the formal consent form that participants will sign to agree to take part in the study. Due to Covid-19, consenting processes have been adapted to ensure that consent is undertaken remotely. The Clinical Research Network have confirmed that the consent form can be posted to participants as part of the initial communication. Prior to Covid-19, consent would have been obtained in a face to face meeting with a healthcare professional.

4. **Decline to Participate Return Slip**
   This will allow a participant to advise the GP practice if they do not wish to take part in the study.

The GP practice will send the information pack above to each potential participant and include a prepaid return envelope for them to return their signed consent form or decline to participate return slip.

The participant will be given three options:

1 Sign and return the consent form if they are happy to take part
2 Sign and return the *Decline to Participate Return Slip* if they do not wish to take part
3 Wait for a telephone call from the GP practice if they require further information before deciding

Patients will then be given one week to decide whether they want to take part before further contact is made with them. After a week has passed, a healthcare professional from their GP practice will call them to discuss the study and if the patient is still unsure, they will be given longer to consider.

More detailed descriptions of the consenting processes is contained in the Consent and Patient Information Sheet (PIS). It will be made very clear to the participants that:

a) their usual care will continue as usual if they agree to join PoC;

b) they will not gain any particular benefit for themselves in health terms but they will be helping others. They will understand that they understand that the PoC is an “observational study”;

c) there will be support on offer to them during the trial by messaging electronically, or by phone and speaking to one of our helpers;

d) they can withdraw from the trial at any time without the need to give a reason; their pseudonymised data cannot be removed and will continue to be used;

e) should they become unwell and lose capacity they will not continue in the research study but their pseudonymised data will be retained and used in the study;

f) they will be informed that the PoC has been approved by the Health Research Authority, which includes Research Ethics Committee review;

g) they will be informed of the outcomes of the PoC at the end of the study;

h) they will be informed that their data being used in the PoC is pseudonymised and they cannot be identified.

Their own GP will not be able to see this pseudonymised data. We will NOT be using face-to-face methods because of precautions to Covid-19. Instead we will be using "participant facing documents" to use in recruitment activities, to explain the study and will be encouraging questions, with the intent of ensuring that they are fully informed in some detail.

From the moment the participant agrees to join the trial, and for the duration of the trial, the participants data will be pseudonymised; the participant will have understood this when they agree to consent.

Commented [CP9]: Needs rewriting to remove the repeated information from recruitment section above and replace with:
Considerations related to:
- Covid-19
- Non-interventional collection of data and blinding of results to participants
- How care home staff will be asked to participate (refer to SOP)
- Any other ethical considerations

7. Monitoring and auditing the study

The Chief Investigator (CI) will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensuring adequate data quality.

The Chief Investigator will inform the Sponsor should concerns arise from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

8. Training

The Chief Investigator/ Coordinator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study site files. A copy of these documents will also be kept at the Sponsor Site. Site inductions will be undertaken by the CI and coordinator in order to train local staff.

9. Assessment and Management of Risk

The following represents a table listing potential risks and mitigations:

Risks	Mitigation
Electrical risk	ActivInsights device is CE Marked and is approved by NHS for Research. Other devices are apps and non-wearable.

Misreading of physiological data	Observational study with no clinical intervention
Vulnerable Patients	CRB Certified support staff at Optima
Data / IG Breach	Following expert advice from NHS X DARS RESEARCH team together with Optum IG and AGEM CSU Team

10. Protocol Deviations and Violations

A deviation is usually an unintended departure from the expected conduct of the study protocol, which does not need to be reported to the sponsor. The Chief Investigator will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree:

a) the safety or physical or mental integrity of the participants of the study (not applicable in this study); or
b) the scientific value of the study.

The Chief Investigator and Sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

11. Recording Adverse Events/ Serious Safety Measures

In the event of an Adverse event, the following information will be recorded and protocol will be followed overseen by the Senior Responsible Officer for South Lincolnshire CCG – Ms. Jo Wright & The Chief Investigator – Professor David Patterson.

Date	Nature of the event	Reported to:	Action taken recorded	Resolution agreed by

12. Reporting and dissemination

Results will be fed back initially to the Study Steering Committee, and subsequently to any associated funding bodies. Results of any studies will be presented at scientific meetings and disseminated in the form of scientific papers.

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