

**Innovation Project Application Form
Salford Innovation and Improvement Fund Locality Call 2022/2023**

Each question in this application form is very specific about the information required. **Please ensure that you read the separate 'Application Guidance' document carefully, complete all sections of this form and provide all the information requested.** Please ensure that any abbreviations/acronyms are explained at the start of the application; they may then be abbreviated throughout the remainder of the application.

SUBMISSION DETAILS

SUBMITTED BY (<i>name, role, org.</i>)	Ulrike Hammerbeck Senior Lecturer in Physiotherapy University of Brighton
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SUBMITTING ORGANISATION	Northern Care Alliance
PARTNER ORGANISATION(S) (<i>if a joint bid</i>)	MDSAS Ltd. (Medical Data Services and Solutions) University of Manchester University of Brighton
DATE SUBMITTED	26. August 2022

<i>Details of how to complete each section of this form correctly are found in the Application Guidance document. Please confirm that you have followed this guidance</i>	<input checked="" type="checkbox"/> I have read and followed the Innovation Fund Application Guidance document
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SECTION ONE: PROPOSAL OUTLINE

1) NAME OF YOUR PROPOSED PROJECT

Feasibility of using a patient-held app to Monitor Arm Recovery after Stroke (MARS) within 3 days of hospital admission.

2) SUMMARY OF PROPOSAL

What are you proposing to do and why? What need are you addressing and what evidence can you provide of that need? (max 1500words)

Delivery of stroke rehabilitation is a significant and costly challenge for the NHS. Stroke care costs £3 billion per annum with additional economic costs of £3 billion from the changes to stroke survivors' independence and life roles. The most common stroke impairment (>50% of admissions) is arm weakness (Kwakkel et al, 2012) with significant impact on quality of life (Morris et al, 2013) and life after stroke (Veerbeek et al, 2013).

Arm recovery after stroke is very poor with a third of stroke survivors with arm weakness at onset, unable to use their arm in function in the long term (Kwakkel et al, 2012). The greatest amount of arm recovery occurs in the first weeks after stroke and it is in this period that high repetition rehabilitation can make real impact on functional recovery through new neural connections, known as neuroplasticity (Kitago et al, 2019). However, it is very clear that insufficient arm therapy is provided to drive neuroplasticity and therefore optimal recovery (Lohse et al, 2014). This is partly because both patients and therapists don't prioritize arm rehabilitation early after stroke (de Wit et al, 2006). Instead, the focus of rehabilitation tends to be mobility to enable earliest discharge (de Wit et al, 2006, Hayward et al, 2015). Additionally, services are not staffed to deliver the intensity of therapy that has been shown to be effective (McCabe et al, 2015, Ward et al, 2019). There is a need to increase stroke survivors' awareness of their arm recovery as early as possible after their stroke and to engage them in their own rehabilitation within the current confines of funded therapy.

We propose that our app; MARS (Monitor Arm Recovery after Stroke), that was co-developed with patient and public involvement (PPI, 7 members), and clinicians with funding from the Small Business Research Initiative, can address this need. Apps provide an opportunity to monitor stroke recovery longitudinally. Patients can increase self-efficacy through a role in their rehabilitation and clinicians can monitor change remotely.

To date we developed an application for patients and healthcare professionals guided by the NICE Digital Evidence Standards Framework which focusses on arm recovery after stroke. The app is patient-held and prompts stroke survivors to upload measures of their arm recovery on a weekly basis. PPI input ensured that the app is easy to use for stroke survivors with visual, cognitive, language and/or dexterity impairments. It requires responses to simple questions and can be completed with text-to-voice and voice-to-text technology. Patients highlighted that the app would provide them a central role in their recovery process and empower them. Patients also value visual depiction of changes of arm function over time. However, they advised to include safeguards (activate/de-activate function) for feedback that may be perceived to be negative.

Clinicians identified the need to monitor arm function, pain, spasticity and fatigue as well as more general measures of quality of life. They advised that the app would provide value as an information portal for contacts, services and care plans for stroke survivors, including home exercises. These can be set-up on the app as hospital/trust specific features and included on a case-by-case basis by simple tick-boxes on the clinician portal. Clinicians felt that the app could address challenges of poor clinical oversight and

information flow between care settings (acute to community). Discharge letters, patient specific outcome measures and 6-month review data can be uploaded and viewed.

The benefits of the app are that they will increase patients' awareness of their arm impairment, provide them a central role in their rehabilitation and collect arm recovery data in the early period after stroke, when most recovery occurs. In addition, the application creates a joined-up information portal for both patients and clinicians.

With the funding requested we want to establish the feasibility of instigating the use of this app, for stroke survivors with arm weakness, in the first three days after stroke. It is very clear that apps could be extremely valuable in the delivery of health care, however whether this is feasible for the clinical population is not well established. Stroke is a disease that occurs predominantly in older adults and is twice as likely in economically deprived individuals. Therefore, it is important to establish whether an app on a smartphone is actually a workable solution because smartphone use is lower (although increasing) in these subgroups (Statista, 2021). The feasibility data from this study will show us if patients take up this opportunity, if they use the app and their thoughts of the app and barriers and facilitators to app use. This information will aid the development of an enhanced application.

The aim of this pilot study is therefore to explore the feasibility, acceptability and preliminary outcomes of a novel, purpose-built app measuring arm recovery in acute stroke survivors.

Experimental details and design of proposed project

Study Design: A prospective, longitudinal cohort study, using experience sampling methodology with patient reported outcome measures (PROMS) ascertained via the smartphone app MARS.

Procedure: Clinical Research Network practitioners at Salford Royal NHs Foundation Trust (SRFT) will approach patients to establish eligibility and consent. A detailed anonymized screening log will be completed for each patient approached with specific reasons why participation was declined (if happy to provide this information). To start participation research practitioners will send a WebApp link to the patient by text or email, assist with download of the app on their or their carers smartphone and demonstrate its use. The practitioners will guide the patient/carer through the first data entry. After the initial contact, the patient or carer will perform all data input prompted by the app. Participants will identify a day of the week to receive prompts to input measures of arm function on the app on a weekly basis for 6 weeks. Our PPI group co-designed the questions and did not perceive them to be too burdensome. For SRFT patients the research practitioner will inform the therapist team (acute setting) that the patient has agreed to participate, and the therapist team will be sent a prompt to access and edit patient records on the clinician portal. The clinicians will receive weekly prompts to view their patient entries and trained to upload information, including discharge summaries. Therapists in the acute setting will need to tick a box and provide an email address to alert the community/early supported discharge team of transfer of care of a patient that is using the app. Subsequently the community team will receive weekly prompts to view and upload information on the app.

Study population: Inclusion criteria: Acute hospital admissions to SRFT with onset of stroke ≤ 3 days, Age ≥ 18 years, upper limb weakness established by National Institute of Health Stroke Scale (NIHSS) upper limb score ≥ 2 . Exclusion criteria: Patients unlikely to survive (e.g. Glasgow Coma Scale < 9 22), patients on palliative pathways, pre-existing neurological/musculoskeletal conditions.

Outcome:

Objective 1: Establish the rate of uptake to participate in the research project

Objective 2: Evaluate reasons for not agreeing to participate in the research project with specific emphasis on establishing if the use of a smartphone app is a barrier.

Objective 3: App data analytics of patient use and clinician use, including: frequency of input, completeness of data input, time (minutes) taken for data input, frequency of view of recovery summary

Objective 4: Analyse measures of arm recovery for weekly measures for 6 weeks.

Objective 5: Qualitative interviews with convenience sample of ~15 participants and ~5 therapists

We will interview ~20 participants to get a broad view of perceptions of the app and app use. We will aim to recruit 5 participants each of:

- stroke survivors who agreed to participate and used the app,
- stroke survivors who agreed to participate but did not use app for the full 6 weeks
- stroke survivors who declined to participate in the study
- clinicians (occupational therapists or physiotherapists) working with individuals that used the app

Our consortium of Medical Data Solutions and Services - MDSAS (specializing in mHealth Solutions), University of Brighton and University of Manchester (expertise in conduct of clinical evaluation of stroke recovery), SRFT as part of the Northern Care Alliance and Greater Manchester Neurorehabilitation & Integrated Stroke Delivery Network (delivery of complex stroke care services) are ideally suited to develop, evaluate and commercialise this app to improve patient care and outcome. We have established PPI and stakeholder consultation groups (GMNISDN) that will continue to be invaluable in guiding development during this project.

Expected outcome:

This project will provide us with clear measures of the feasibility and acceptability of the app for acute stroke survivors admitted to SRFT. It will also provide us with pilot data of measures of arm recovery entered on the app.

Use of this system will make major contributions to stroke care, enabling patients to be involved in their own care, giving health care professionals better understanding of patient's recovery trajectories; permitting early intervention and rapid escalation of care, providing a joined-up information portal for both patients and clinicians and a rich epidemiological database to explore stroke recovery.

3) KEY OBJECTIVES: WHAT ARE YOU TRYING TO ACHIEVE?

(Key things that need to happen for the project to be considered successful)

These objectives need to be **SMART (Specific, Measurable, Achievable, Realistic and Timed)**. Project objectives and associated payments need to be completed within the 12 month period after the agreed project start date.

If the project has more than five objectives, please list additional objectives in the comments section.

Objective 1:	To establish the uptake of the use of a smartphone app to monitor arm recovery (MARS) in stroke admissions with arm weakness at SRFT within three days of stroke.
Objective 2:	To establish the extent of a barrier, access to a smartphone poses for the uptake of this app in eligible stroke survivors.
Objective 3:	To monitor patient and clinician engagement with the app for a 6-week follow-up period with regards to completion of measurements and use/view of recovery metrics.

Objective 4:	To evaluate recovery metrics entered by stroke survivors through patient reported outcome measures (PROMS).
Objective 5:	To establish participants' view of the app, the need for an app and barriers and facilitators to use through qualitative assessment in a convenience sample of 15 patients and 5 clinicians.

Comments:

4) WHICH CITIZENS / PATIENTS / COMMUNITIES / VULNERABLE GROUPS WITHIN SALFORD WILL SEE A BENEFIT AS A RESULT OF THIS PROPOSAL?

Group/s	What benefit/s will be realised for this particular group?
<p>Stroke survivors with arm weakness</p> <p>An average of 150 stroke survivors are admitted to SRFT every month. Arm weakness occurs in ~2/3 of stroke admissions. We therefore foresee that this application could be beneficial to up to 100 individuals per month who could be using this app for a year or longer.</p>	<p>Direct: Stroke survivors will benefit by being central in their care pathway. The application will be patient-held which will increase self-efficacy. Stroke survivors will be able to view metrics of their recovery over time which will be empowering. The app will be a centralised information portal that provides all up-to-date advice and information to the patient.</p> <p>The app will provide additional care by allowing clinicians to monitor stroke survivors progress remotely. The app will allow remote intervention which could reduce the need for repeat hospital visits. The app can alert clinicians to unexpected changes in recovery metrics. The app will also allow patients to communicate with clinicians.</p> <p>Indirect: The app will increase care efficiency by improving information and data flow between services (acute in-patient to community). This could include home exercise programmes, discharge letters, rehabilitation goals and 6-month review.</p> <p>An additional indirect benefit is that this application will also provide researchers with an invaluable large dataset of arm recovery of stroke survivors. This information will inform future research to improve the outcome for stroke survivors.</p>

5) HAVE YOU PREVIOUSLY SUBMITTED ANY APPLICATIONS FOR FUNDING TO DELIVER THIS PARTICULAR INNOVATION WITHIN SALFORD?

Please tick the relevant box, and provide details where necessary

	Details
<input checked="" type="checkbox"/> No	
<input type="checkbox"/> Yes – and it was not funded	
<input type="checkbox"/> Yes – and it was funded	

6) HAS YOUR PROPOSED IDEA BEEN IMPLEMENTED OUTSIDE OF SALFORD PRIOR TO THIS APPLICATION?

(If yes, please state where, when and provide details of the impact of this in the comments section below)

- Yes
 No

Comments:

7) PLEASE EXPLAIN HOW THIS PROPOSAL IS “INNOVATIVE”

Provide a short but clear rationale as to why and how this proposal constitutes an “innovation” for Salford. For example, is it a completely new product /idea /process /service /way of working? Is it something that has worked well elsewhere but is new to Salford? Is it something that has worked well in another field/industry and has potential to transfer to a new purpose in health and social care? We expect applicants to have performed some preliminary research or scoping into what activities and programmes of work are already underway in Salford and Greater Manchester in their chosen topic area to ensure that their proposal would complement, and not duplicate, existing local or national initiatives.

This is a new technology that has not been implemented in Salford or elsewhere. Currently arm recovery is not prioritised early after stroke and is not monitored when patients leave hospitals except if they have follow-up therapy appointments either at the hospital or in the community. To our knowledge no patient-held app monitors arm recovery from admission.

This new app has a clear potential to improve patient care and increase therapy efficiency. It will place patients central in their arm recovery and inform them of progress. It will be a central information portal and assist in data flow between clinical settings. It will additionally provide clinicians remote access to monitor change and intervene and prioritise patients that most need input. Therapist may be able to provide input remotely. This is attractive to minimize hospital visits for patients, time taken for home visits for therapists and beneficial for environmental sustainability. Other rehabilitation applications deliver a specific rehabilitation but don't capture recovery data as a primary outcome. We specifically will address the question of whether an application is an appropriate measurement tool for stroke survivors by collecting reasons for declining participation and including individuals who decline to participate in our qualitative analysis.

The prototype has been developed with assistance from a PPI group (7 members with diverse difficulties, 5 women, age 22-78) and the rehabilitation subgroup from the Greater Manchester Neurorehabilitation and Integrated Stroke Delivery Network (GMNISDN). Collaborating directly with the GMISDN (who have influence on local budget holders) allows implementation of the application in the NHS, pursuit of procurement and wider implementation at pace throughout Greater Manchester.

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SECTION TWO: ALIGNMENT WITH SALFORD LOCALITY PRIORITIES

8) WHICH OF THE 2022-23 INNOVATION PRIORITIES DOES YOUR PROPOSAL ADDRESS?

(This year's Innovation Priorities are summarised below. Please tick the ONE most relevant box for the priority area your proposal aligns with.)

2022-23 Innovation and Improvement Themes	
<input checked="" type="checkbox"/>	Neighbourhood based care
<input type="checkbox"/>	Safer Salford Care Homes and Domiciliary Care
<input type="checkbox"/>	Workforce Transformation
<input type="checkbox"/>	Sexual Health
<input type="checkbox"/>	Frailty and ageing
<input type="checkbox"/>	Screening
<input type="checkbox"/>	Tackling vaccine / immunisation hesitancy

A full breakdown of these themes is available in the separate Application Guidance document.

NONE / OTHER	<input type="checkbox"/>	Please select this option if your proposal does not clearly align to any of the above priority topics, but you believe it addresses a current un-met need
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9) WHICH OF OUR CORE INNOVATION PRINCIPLE/s DOES YOUR PROPOSAL EVIDENCE?

(Please tick all that apply)

<input checked="" type="checkbox"/>	Exploiting the use of Technology and Digital Innovation
<input checked="" type="checkbox"/>	Partnership Working - Developing links between Health & Social Care and external organisations that are looking to test and evaluate innovative solutions in this field
<input checked="" type="checkbox"/>	Neighbourhood Working - Developing, delivering and structuring Health & Social Care within the 5 Salford Neighbourhoods / GP Networks
<input checked="" type="checkbox"/>	Addressing Health Inequalities and Wider Determinants of Health
<input checked="" type="checkbox"/>	Improving the Environmental Sustainability of care

The primary innovation principles of this project are exploiting the use of **technology and digital** innovation, **partnership** and **neighbourhood** working.

However, we will also directly address **health inequalities** because stroke survivors are of an older demographic. The use of a smartphone could potentially exclude older stroke survivors and individuals from lower income groups. We acknowledge that not everybody in the UK owns a smartphone, however, relatives or caregivers often do. Smartphones

now represent 92% of UK mobile use (Statista, 2021) and although use is still lower in older individuals, in the age of over 65-year-olds, it has increased from 3% to 65% in the last eight years (Statista, 2021). Only 10% of UK households have no access to a smartphone (Deloitte, 2019), which would prevent participation in our research study. Previous PPI work indicated that patients' relatives value a role during rehabilitation, which could include assistance with data input. App usage should not increase network charges as the data files for this app are very small with limited impact on data transfer costs. Stroke survivors can be hard-to-reach because of the impairments that they present with, including aphasia, a difficulty with speaking, reading or understanding. We have designed the app to be aphasia friendly with large font, simple layout, pictorial options and voice-to-text and text-to-voice functionality. In the development of the app we have included individuals with diverse demographics and diverse background in our PPI group to improve acceptability of the design for all. Although the app is not primarily designed to, it has the potential to additionally address **environmental sustainability** in the future. The app will provide clinicians the possibility to monitor recovery remotely, be contacted by the patient and to receive notifications of any unexpected, detrimental changes in recovery measures.

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SECTION THREE: PROJECT DELIVERY

10) KEY PROJECT TIMESCALES

(What is expected to happen, when?)

Month 1	Steering group meeting: PPI, GMNISDN representative and all collaborators Complete and submit ethical and R&I approval with assistance of PPI Induct staff <ul style="list-style-type: none"> • Qualitative researcher to start as early as possible • Clinical Research Network practitioner to start at 2 months after onset Format app for roll-out and set-up system hostings (MDSAS) Set up study protocols and systems
3 months:	Steering group meeting Ethical approval in-place Start recruiting (recruitment to run for 3 months) Collect data about decision to participate and reasons why not Collect follow-up data for first 6 weeks Identify qualitative interview sample (20; 15 stroke survivors, 5 clinicians) Perform interviews
6 months:	Steering group meeting End recruitment Collect follow-up data for first 6 weeks (cont.) Identify sample for qualitative analysis (cont.) Perform interviews (cont.) Extract data from app platform (usage and measures of arm recovery)
9 months:	Steering group meeting Analysis <ul style="list-style-type: none"> a) Feasibility data b) Qualitative analysis Optimise app with feedback from QA, interviews and reasons for not taking up research opportunity Write-up
12 months:	Steering group meeting Dissemination – conferences, prepare paper for publication Optimise app in-line with feedback from interviews Apply for follow-up funding

11) HOW IS THE PROJECT GOING TO BE MANAGED?

Project Management

Project manager:

- Dr Ulrike Hammerbeck, Senior Lecturer in Physiotherapy, University of Brighton, will hold an honorary contract at Salford Royal NHS Foundation Trust (agreed). She will perform all induction of staff and attend all steering group meetings in person but manage the majority of the [project remotely]. Dr Hammerbeck has extensive experience working within the Manchester academic environment, Salford Royal NHS Foundation Trust and Greater Manchester Neurological and Integrated Stroke Delivery Network (GMNISDN). She is moving to a part-time post at Brighton University in November 2022 and will therefore have capacity to run this project.

- 0.2FTE funded through this project
- Weekly meetings to monitor and guide progress, delegate actions and supervise staff
- 3-monthly steering group meetings with PPI, GMNISDN representatives, MDSAS and all research staff to track task completion and evaluate effective risk mitigation

Dr Hammerbeck (UH) will lead the team which will consist of:

- Dr Rob Hollingsworth (MDSAS), Director of our business partner MDSAS Ltd. (Medical Data Solutions and Services)
- Dr Adrian Parry-Jones (AP-J), Reader in Neurology, SRFT and University of Manchester
- Dr Lisa Brunton (LB), Research Fellow, University of Manchester
- Band 4 Clinical Research Network Practitioner (CRN_P) – 0.5FTE for 4 months, SRFT (month 2-6 of study)
- Band 6 Qualitative Researcher (QualR) – 0.5FTE for 12 months, University of Manchester

The two posts will be advertised as early as possible. We have discussed recruitment into these posts with the lead for the CRN, Louise Harrison and a senior Qualitative researcher we are collaborating with currently, Dr Lisa Brunton and they have both indicated that it would be easy to recruit for these roles as the posts would be seen as attractive. Dr Brunton has also agreed to provide additional supervisory expertise to the qualitative research processes.

Responsibilities for individual deliverables

Deliverables:

- Complete study protocol UH, AP-J, QualR (LB)
- Ethics application and approval UH, AP-J, QualR, PPI members
- App preparation and set-up system hosting MDSAS
- Ongoing app support for study participants via QA MDSAS
- Recruitment CRN_P
- Identify participants and perform qualitative interview QualR
- Extract data from app platform MDSAS
- Optimise app with feedback MDSAS
- Analyse data QualP (LB), UH, AP-J
- Progress report UH, AP-J, RH, QualR
- Final reports UH, AP-J, RH, QualR
- Dissemination UH, AP-J, QualR (LB)

Internal reporting and governance processes for the project

The Northern Care Alliance will sponsor the study, providing oversight of conduct throughout. Dr Hammerbeck will provide leadership, supervising the research fellow and assistant (weekly remote meetings) and engaging with co-investigators, and the service-user advisory group at pre-defined three-monthly time points to mitigate risks to the project. The Research Associate will be a senior qualitative researcher and will be supported by Dr Hammerbeck and Dr Parry-Jones (Dr Lisa Brunton). The Northern Care Alliance, as the host institution will oversee financial management.

Dr Hammerbeck and the Research Associate will work with the sponsor and collaborators, and the Clinical Research Network to:

- Develop the study protocol in accordance with STROBE and COREQ

- Provide oversight of project set-up including submissions for regulatory approval, data management plans, employment of staff, contracts
- Ensure project delivered within agreed time frames and within budget
- Provide continued project management including substantial amendments, progress and final report
- Lead on preparation of publication, dissemination and next steps

Research governance principles and ethical committee approvals bind all applicants and their institutions. Dr Hammerbeck will ensure that the study adopts the highest standard of research conduct. Ethical approval will be provided by Northwest - Greater Manchester Central Health Research Authority or other Ethics boards as allocated. The study team has extensive experience of gaining ethical approval for similar studies and will start the application process as soon as informed about funding.

12) HOW WILL YOU MEASURE AND EVALUATE YOUR PROJECT?

A) Does your proposal involve an external / independent evaluation?

- Yes
 No

B) Who will be carrying out the evaluation of this project?

The evaluation of the project will be performed by the Qualitative researcher (University of Manchester) supported by senior academic staff (UH – University of Brighton, LB - University of Manchester and AP-J – University of Manchester).

C) Please outline your plan for measurement and evaluation of the project

In this project we propose to measure the feasibility of the app through patient feedback, app usage, app data and detailed qualitative interviews. This is in line with analysis proposed through the NICE Digital Evidence Standards Framework.

The project will produce two sets of outcomes:

1. Feasibility and acceptability outcomes
2. Qualitative research

Feasibility and acceptability assessment

- 1) Uptake of research opportunity in eligible stroke survivors (percentage)
- 2) Reasons for not taking up this opportunity (for those happy to provide this)
- 3) Completeness of data entry by i) patients ii) clinicians (percentage)
- 4) Amount of usage of the app by i) patients ii) clinicians (frequency and minutes)
- 5) Metrics of arm recovery outcome measures (PROMs)

Qualitative interviews will be performed with a convenience sample of ~15 participants and ~5 therapists to get a broad view of perceptions of the app and app use.

We will aim to recruit 5 participants that are:

- stroke survivors who agreed to participate and used the app,
- stroke survivors who agreed to participate but did not use app for the full 6 weeks
- stroke survivors who declined to participate in the study
- clinicians (occupational therapists or physiotherapists) working with individuals that used the app at SRFT and in the community

Commented [UH1]: B) Who will be carrying out the evaluation of this project?
Please confirm who will deliver the evaluation – e.g., name of University /Academic provider, 3rd party Evaluation partner, specialist division within your org, or the name/role of internal member of the team who will carry out the evaluation activities.
If your proposed project is significantly large in its scale or scope, an independently led or externally provided evaluation would be more appropriate in order to maintain the robustness and objectivity required of evidence needed at this scale.
C) Please outline your plan for measurement and evaluation of the project
Describe the measurement and evaluation plan for this project. This should cover, as a minimum, the following details:
• How you will measure and demonstrate impact
• How you will evaluate what works, and what doesn't
• What data you will be collecting
• How often you will collect these data and from where
• How you will analyse these data
Some basic guidance for internal evaluation can be found online [HERE](#)
If you are uncertain about measurement and evaluation for your project, or want a particular level of evaluation, you may wish to involve an external evaluation provider as a partner organisation for this proposal.
We have found such partnerships particularly effective in delivering high quality evaluations, and costs for the provision of this external evaluation support/delivery are welcome to be included in your funding request. These costs should be described in your budget within section 3 of the form.
As an indicative figure, we have found that the most successfully evaluated programmes have allocated a budget of around 5-10% of their total funding amount requested towards evaluation activities.

The qualitative evaluation will be aligned to the behavioural change wheel and COM-B model (Michie et al, 2010) to optimise the implementation of the application in clinical practice.

The data from the above streams will be combined to:

1. Update and optimize the app for future use
2. Write a scientific evaluation of the feasibility and acceptability of app use in acute stroke that will be published in a peer reviewed journal and presented to the GMNISDN group and at their conference.

13) WILL THE PROJECT REQUIRE A CHANGE TO AN ESTABLISHED CARE PATHWAY?

If you are currently unable to assess if the activity will require a change to an established pathway, please indicate so using the Don't Know option. Applications selected to progress will be able to work with their sponsor to establish this.

- Yes
- No
- Don't Know

If Yes, please provide details of the existing care pathway and explain how your project will require a change to this.

The care pathway will not change however, clinicians will be able to provide information of support systems (Stroke Association Contact, My Stroke Guide Information, local support networks and social services contact) and home exercises on the app by tick boxes on the clinician portal rather than in paper format.

14) IS THIS A DIGITAL HEALTH TECHNOLOGY (DHT)?

- Yes
- No

IF YES, please answer the below questions:

A) How would you categorize the function of this Digital Health Technology (DHT)?
(tick **ONE** option only)

	Functional Classification	Description	Examples May Include
<input type="checkbox"/>	System service	Improves system efficiency . Unlikely to have direct and measurable individual patient outcomes.	Back office systems, Electronic prescribing, health record platforms, Ward management systems.
<input type="checkbox"/>	Inform	Provides information and resources to patients or the public. Can include information on specific conditions or about healthy living.	DHTs describing a condition and its treatment. Apps providing advice for healthy lifestyles (such as recipes). Apps that signpost to other services.
<input type="checkbox"/>	Health Diaries	Allows users to record health parameters to create health	Health tracking information such as from fitness wearables.

		diaries. This information is not shared with or sent to others.	Symptom or mood diaries. No data transmitted.
<input type="checkbox"/>	Communicate	Allows 2-way communication between users and professionals, carers, third party organisations or peers. Clinical advice is provided by a professional using the DHT, not by the DHT itself.	Instant messaging apps for health and social care. Video conference-style consultation software. Platforms for communication with carers or professionals.
<input type="checkbox"/>	Preventative behaviour change	Designed to improve health behaviours to prevent ill health consequences associated with smoking, eating, alcohol use, sexual health, sleeping and exercise. Based on accepted behaviour change theories	Smoking cessation DHTs and those used as part of weight loss programmes. DHTs marketed as aids to good sleep habits.
<input checked="" type="checkbox"/>	Self-manage	Aims to help people with a diagnosed condition to manage their health . May include symptom tracking function that connects with a healthcare professional	DHTs that allow users to record, and optionally to send, data to a healthcare professional to improve management of their condition.
<input type="checkbox"/>	Treat	Provides treatment for a diagnosed condition (such as CBT for anxiety), or guides treatment decisions.	DHTs for treating mental health or other conditions. Clinician-facing apps that advise on treatments in certain situations. Electronic prescribing systems that provide patient-level advice on prescribing.
<input type="checkbox"/>	Active Monitoring	Automatically records information and transmits the data to a professional, carer or third-party organisation, without any input from the user, to inform clinical management decisions.	DHTs linked to devices such as implants, sensors worn on the body or in the ward/home/care setting. Data automatically transmitted through for remote monitoring.
<input type="checkbox"/>	Calculate	Tools that perform clinical calculations that are likely to affect clinical care decisions.	DHTs for use by clinicians, professionals or users to calculate parameters pertaining to care, such as early warning system software.
<input type="checkbox"/>	Diagnose	Uses data to diagnose a condition in a patient, or to guide a diagnostic decision made by a healthcare professional.	DHTs that diagnose specified clinical conditions using clinical data. AI systems making diagnostic or triage decisions.

Functional Classifications from NICE Evidence Standards Framework for Digital Health Technologies (April 2021)

B) Does the Digital Health Technology have a CE mark?

- Yes
 No

C) Is the Digital Health Technology classed as a medical device?

- Yes
- No

If yes, please state classification and whether currently approved by MHRA

15) WILL YOUR PROPOSED PROJECT ACTIVITY REQUIRE ACCESS TO, CHANGES TO, OR INTEGRATION WITH, EXISTING IT SYSTEMS TO ENABLE DELIVERY?

- Yes
- No
- Don't Know

Please only select the 'Don't Know' option if you are currently unable to assess whether the activity will require access or changes to IT systems or infrastructure. If selected for progression, you will need to engage the relevant IT departments of pilot sites to complete this assessment and establish any requirements prior to achieving final sign-off for funding.

If Yes, please answer the below questions:

A) Which system/s or infrastructure will you require access to, changes to, or integration with?

n/a

B) What changes / integrations are required, and the timescales needed for this?

n/a

C) Who owns or manages this system / infrastructure?

The project will utilise the existing and proven MDSAS patient support app for which the IP is wholly owned by MDSAS. This includes the adaptations for its use within stroke which have been made during our Small Business Research Initiative project. As such there are no IP constraints in our ability to utilise the application for this feasibility study. This will help greatly to simplify income models and procurement into NHS organisations whilst maximising potential growth for MDSAS as an SME. Stroke is a new market area for MDSAS which has significant commercial potential to grow the local Manchester company.

Searches have been carried out to establish if there are any restrictions on our freedom to operate and these have not highlighted any. We have also carried out searches (including literature and web) to establish if any similar software solutions exist and although there are apps in use that support remote consultation, we have not found any with the same functionality in a single application for optimising arm recovery from stroke.

The application functionality has been designed to be applicable to multiple stroke domains such as walking, cognition and fatigue. Introduction of the project into these wider stroke domains has the potential to expand and improve the IP related to the functionality of the application. Project foreground IP will be managed by MDSAS with partners retaining any background IP brought to the project.

D) How have you engaged with the relevant system owners / managers / IT departments so far to determine the feasibility of making these necessary changes?

The app will be delivered independently and will not require any changes to IT systems.

16) WHAT RISKS HAVE YOU IDENTIFIED FOR THIS PROJECT, AND HOW WILL YOU MITIGATE THEM?

Key project risks (and mitigation):

Project delivery

Delay with achieving ethical approval

- We have extensive experience in securing HRA approval and will submit an application as soon as we receive outcome from this application.
- Versions of the app are already approved and in use throughout the NHS with over 2 million entries from patients

Poor recruitment to project

- The recruitment rate is part of our feasibility outcomes. We will collect information of why individuals chose not to take part in a detailed screening log to inform changes to the provision of this app in future.
- An average of 150 strokes are admitted to SRFT a month and 2/3 of these could have arm weakness. We propose to approach all individuals with arm weakness before 3 days after stroke for participation. This could provide us with up to 300 potential participants. Even if we would only recruit a quarter of these individuals, we will have substantial data for 75 participants as well as the data on why individuals decided not to participate and qualitative interviews.

Difficulties with app usability (patient and clinician)

- We will identify any issues and rectify via software QA delivered by MDSAS. We will take any feedback forward for app optimization on completion of the project

Technical including data protection and security

Patients uncertain about data security and refuse use of app

- produce patient information with assistance of our PPI members to ease concerns and continue to engage with patients, and healthcare professionals to clarify any arising uncertainties.

Difficulties with NHS information governance approval to operate

- The app is already approved and in use throughout the NHS with over 2 million entries from patients

Commercial

Market place competition

- searches indicate no direct competition for the functionality provided within a single application

Commercial risk of IP ownership

- The IP is owned by MDSAS and thereby there will be no limitation of app use as they are a partner in this application.

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SECTION FOUR: BUDGET & FINANCE

17) WHAT IS THE TOTAL AMOUNT OF FUNDING YOU ARE REQUESTING?

This must be a set figure – requests for variable amounts will not be accepted. Please ensure the amount stated is fully inclusive of all VAT

£72,112

Payment schedules for successfully funded projects will be finalised prior to sign-off. The typical arrangement is to pay 50% of awarded funds up front, with the remaining 50% released upon receipt of a successful 6-month project update report. If you would require any different payment schedule or arrangement, please give details below

18) PLEASE PROVIDE A FULL BREAKDOWN OF HOW THE REQUESTED FUNDS WILL BE UTILISED

Please include a comprehensive budget, ensuring you include VAT where applicable.

Staff	Period	FTE	Band	Cost
Ulrike Hammerbeck - Project Manager	12 months	0.2	7 pt44	£13800
Research fellow	12 months	0.5	6 pt36	£31800
Research Assistant (CRN)	4 months	0.5	4	£5112
Adrian Parry-Jones	12	0.05		£6310
Digital expertise (MDSAS)	12			£9800
Sub-Total				£66822

Task				Cost
System hosting	Supported by MDSAS			£2020
PPI travel	3 members	5 visit	£30	£450
PPI time	3 members	7 hour	£25	£525
Travel to steering meetings (UH)	1 member	7 visit	£111.90	£783
Transcription (incl VAT)	20 interviews	45min	£1.4/min	£1512
Sub-Total				£5290

Total				£72112
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The staffing of the project includes a project manager who will be working on this project one day a week. Ulrike Hammerbeck is a senior lecturer in physiotherapy and has been instrumental in developing this app with MDSAS. She has extensive experience of working within the stroke unit at SRFT (having recruited with assistance of the CRN for previous projects) and has been working with Adrian Parry-Jones, GMNISDN and the PPI group members on this and other projects. Dr Hammerbeck will be taking up a part-time post at the University of Brighton in November and will therefore have capacity and expertise to lead this project.

The study is dependent on qualitative analysis of app use. We have costed for a senior qualitative researcher on a part-time basis (0.5FTE) for the whole project period. This researcher will have additional support from Dr Lisa Brunton of University of Manchester. The project has to start within two months of notification of funding and we will recruit this post internally from University of Manchester. We believe that this will be an attractive post and have been told by a current collaborator (Lisa Brunton) that recruitment to this post should not be difficult.

The post of a research assistant will be housed within the clinical research network and we will recruit to this post as soon as possible with assistance from Louise Harrison, Lead Nurse for the Clinical Research network.

We have included expenses for the expertise of our business partner (MDSAS Ltd.) to finalise and host the app. They will provide support for users and extract the data at completion of data collection.

We have included costs for our PPI members to attend the five steering group meetings and Dr Hammerbeck to travel from Brighton to attend these meetings in person. We have included two additional train fares to allow travel for induction for the two staff members. Transcription costs of 20 interviews have been included on the base of lasting ~45minutes, consisting of two voices and to be recorded by teams or telephone conversations.

19) HOW WILL THE PROJECT ACHIEVE A RETURN ON INVESTMENT / COST BENEFIT?

We believe that this project offers good value for money for The Salford Integrated Care Partnership with significant potential for Return on Investment (ROI) in future.

The longer-term financial ROI is envisaged to occur through improved patient care and better outcomes of arm recovery for stroke survivors. Better data transfer between care settings and the possibility for therapists to remotely monitor and be alerted to detrimental change will improve care and outcome. The app is designed to increase patients' engagement in their rehabilitation which should lead to better self-management and thereby better outcomes.

The app will improve efficiency of therapy provision. The ability to remotely monitor progress will allow clinicians to identify who required intervention most urgently and thereby direct their resources accordingly. Clinicians will be able to include information on support systems (Stroke Association Contact, My Stroke Guide Information, local support networks and social services contact) and home exercises on the app by tick boxes on the clinician portal rather than in paper format. These processes will save time and increase efficiency.

Stroke poses a huge direct and indirect cost on society. Better arm recovery will allow stroke survivors to be less dependent on carers and improve their ability to return to previous life-roles, including work. As there are an estimated 100 stroke survivors with arm weakness admitted to SRFT each month, this app has the potential to have a large return on investment for the Salford Integrated Care partnership. In future we propose to add additional domains of stroke impairment to the app, including language and cognitive impairment. This will further increase the number of individuals affected by stroke who could benefit from the app.

The project is not designed to provide an immediate financial ROI however, stroke survivors who participate will have the benefit of the use of the application.

20) WHAT COMES NEXT AFTER THIS FUNDING? HOW WILL YOU ENSURE THAT ACTIVITIES, OR RESULTS, ARE SUSTAINABLE AFTER THE 12 MONTH FUNDED PERIOD HAS ENDED?

The findings from this study will be used to optimize our app, MARS.

Findings from the proposed project will be vital for the design of a definitive trial to establish whether the use of MARS improves rehabilitation efficiency, cost effectiveness and the amount of arm recovery after stroke. We will seek funding to role this enhanced application out across Greater Manchester (GM) through collaboration with GMNISDN and perform a robust evaluation seeking patient and clinician views with emphasis on hard-to-reach groups.

We are awaiting outcome from a SBRI stage 2 application which will develop further functionality in MARS and include monitoring recovery in other domains of impairment after stroke, including language and cognition.

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SECTION FIVE: DATA PRIVACY IMPACT ASSESSMENT

21) WILL THE PROJECT COLLECT / USE / PROCESS PERSONAL CONFIDENTIAL DATA?

- Yes
 No

If 'yes', please tick below which of the personal and sensitive data items the asset / system /project will process.

Personal Data Items

- Forename(s)
 Surname
 Address
 Postcode
 Date of Birth
 Home Telephone Number
 Mobile Telephone Number
 Other Contact Number
 GP Name and Address
 Legal Representative Name (Next of Kin)
 NHS Number
 National Insurance Number
 Photographs / Pictures of persons
 Other – please state below:

Sensitive Data Items

- Gender
 Religion
 Ethnic Origin
 Medical Information
 Occupation / Employment
 Other – please state below:

A Data Privacy Impact Assessment (DPIA) form will need to be completed if your proposal is shortlisted to Interview.

- *If Yes is selected, a full DPIA will need to be completed*
- *If No is selected, the DPIA only needs to be completed up to Screen 5*

Form Continues on Next Page

SECTION SIX: SOCIAL VALUE, EQUALITY AND INCLUSION

22) EQUALITY & DIVERSITY POLICY AND COMPLIANCE

A) Do you have an up-to-date Equal Opportunities (or equivalent) Policy in place?	
<input checked="" type="checkbox"/>	Yes
<input type="checkbox"/>	No

The study will be delivered through the Northern Care Alliance and we will therefore follow their equality, diversity and inclusion policy.

<https://www.northern-care-alliance.nhs.uk/about-us/equality-diversity-inclusion>

B) Have you been involved in any Equality Act 2010 litigation breaches in the last 3 years?		
<input type="checkbox"/>	Yes	<i>If Yes, please give details here</i>
<input checked="" type="checkbox"/>	No	

23) PLEASE DESCRIBE HOW THIS PROJECT WILL ENSURE THE RIGHTS OF PROTECTED CHARACTERISTICS IN PARTICIPANTS, AND CONTRIBUTE TOWARDS TACKLING HEALTH INEQUALITIES IN SALFORD?

The app is already approved and in use throughout the NHS with over 2 million entries from patients. The project will utilise the existing and proven MDSAS patient support app for which the IP is wholly owned by MDSAS. This includes the adaptations for its use within stroke which have been made during our Small Business Research Initiative project.

The app will be delivered independently and will not require any changes to IT systems. However, as information governance (IG) approval is often a delay and barrier to adoption and implementation of applications in the NHS, MDSAS have addressed this and are registered and compliant with the NHS Digital Data Security and Protection toolkit (DSP), required for organisations handling sensitive NHS patient identifiable data. MDSAS also has Cyber Essentials Plus accreditation which provides additional assurance on security of MDSAS systems. Our approach to use a re-purposed app that it is already IG approved and widely used in the NHS simplifies adoption. MDSAS with its multi-site implementation experience is also familiar in dealing with individual NHS organisational IG requirements, such as completion of Data Privacy Impact Assessments (DPIAs) and Data Sharing Agreements.

It is very clear that apps could be extremely valuable in the delivery of health care, however whether this is feasible for the clinical population is not well established. Stroke is a disease that occurs predominantly in older adults and is twice as likely in economically deprived individuals. Therefore, it is important to establish whether an app on a smartphone is actually a workable solution because smartphone use is lower (although increasing) in these subgroups (Statista, 2021). The feasibility data from this study will show us if patients take up this opportunity, if they use the app and their thoughts of the app and barriers and facilitators to app use. This information will aid the development of an enhanced application.

We acknowledge that not everybody in the UK owns a smartphone, however, relatives or caregivers often do. Smartphones now represent 92% of UK mobile use (Statista, 2021) and although use is still lower in older individuals, in the age of over 65 year olds, it has increased from 3 to 65% in the last eight years (Statista, 2021). Only 10% of UK households have no access to a smartphone (Deloitte, 2019), preventing participation in our research study.

Stroke survivors can also be a hard-to-reach group because of the impairments that they present with, including aphasia, a difficulty with speaking, reading or understanding. We have designed the app to be aphasia friendly with large font, simple layout, pictorial options and voice-to-text and text-to-voice functionality. In the development of the app we have included individuals with diverse demographics and diverse background in our PPI group to improve acceptability of the design for all.

24) ADDED SOCIAL VALUE: WHAT OTHER SOCIAL, ENVIRONMENTAL OR ECONOMIC BENEFIT/s WILL SALFORD RECEIVE THROUGH THIS PROJECT?

This project offers additional benefits towards net zero policy and environmental sustainability by supporting remote management of patients and providing a platform for early intervention. This has the benefit of reducing both patient and ambulance journeys, reducing emissions and traffic congestion.

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SECTION SEVEN: OPERATIONAL DETAILS

25) REGISTERED DETAILS OF BIDDING ORGANISATION/S

Name of Organisation	Registered Address	Organisation Type
Salford Royal NHS Foundation Trust part of the Northern Care Alliance	Stott Ln, Salford M6 8HD	NHS Trust
University of Brighton	Village Way, Brighton BN1 9PH	HEI
University of Manchester	176 Oxford Rd, Manchester M13 9PL	HEI
Medical Data Solutions and Services (MDSAS Ltd.)	City View House, 5 Union Street, Ardwick, Manchester, M12 4JD	SME

26) WHICH ORGANISATION WOULD THE GRANT FUNDS BE PAID TO?

Please note that funding will only be paid to registered organisations, and not to individuals

The Northern Care Alliance

27) WHO WILL BE THE INDIVIDUAL/S RESPONSIBLE FOR THIS PROJECT?

(Please complete all sections)

SENIOR LEAD <i>(overall accountability and oversight of project)</i>	
Name	Ulrike Hammerbeck
Job Title	Senior Lecturer
Organisation	University of Brighton
Email Address	Ulrike.hammerbeck@manchester.ac.uk
Telephone Number	07879642853

OPERATIONAL LEAD <i>(day-to-day delivery of project)</i>	
Name	Ulrike Hammerbeck
Job Title	Senior Lecturer
Organisation	University of Brighton
Email Address	Ulrike.hammerbeck@manchester.ac.uk
Telephone Number	07879642853

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SECTION EIGHT: APPLICANT AGREEMENT

28) PLEASE CONFIRM THAT IF YOUR PROPOSAL IS ACCEPTED YOU ARE AWARE OF, AND AGREE TO, THE FOLLOWING CONDITIONS:

Applicants must tick all boxes to indicate that they agree to all conditions

<input checked="" type="checkbox"/>	Bidding organisation must be able to confirm a commencement date for the project within 2 months of receiving funding approval or approval may be withdrawn
<input checked="" type="checkbox"/>	Completion of a 6 month (mid-point) project update report, presented to the Innovation and Research Oversight Group (IROG) and relevant Sponsoring Strategy Group
<input checked="" type="checkbox"/>	Completion of a 12 month (final) evaluation report, presented to IROG and the relevant Sponsoring Strategy Group

29) PLEASE CONFIRM THAT YOU HAVE READ AND ACCEPT THE TERMS AND CONDITIONS

- I have read and accept the Salford Innovation & Improvement Fund Terms & Conditions

End of Application

Your completed application form, along with any requested additional information, should now be submitted via email to innovation.salfordccq@nhs.net

You will receive confirmation of receipt within three working days, along with a unique Bid Reference for managing your application and for on-going communication regarding your proposal.

Applications can be withdrawn at any time, for any reason, by contacting innovation.salfordccq@nhs.net with your Bid Reference

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