

**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.**

**STAGE 2: Queries from Stage 1**

**1. Says product is not a Digital Health Technology in Q14 but could this be double checked please, and any additional info provided as to registrations etc (it reads that the technology requires clinicians to monitor the use of the app by patients - in which case this is absolutely a DHT)**

*This is correct, the app is a Digital Health Technology and in Q14 we answered 'Yes' to the question. However, it is not a medical device, as classified by the MHRA (question 14 c) as it is not providing any care but will just monitor recovery and thereby act as/replace paper notes which are similarly not classified as a medical device.*

*The application is fully accredited and already in use in multiple NHS settings including haemophilia, Immunoglobulin therapy and hereditary angioedema and has over 2 million NHS entries. Our business partner, MDSAS has strength in this field because they 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 already Information Governance (IG) approved in NHS settings 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.*

**2. Ethics could pose a considerable delay - has this process been initiated yet at all? If not how will this risk be mitigated?**

*The ethical approval application for this project has not been initiated. However, the research team is submitting an ethics application in the coming weeks for a related project that is comparing arm recovery between acute (<3days) ischaemic stroke and intracerebral haemorrhage patients. We foresee that large parts of this application will pave the way for the application required for this project. We will start the preparation of the ethics application with support from the Geoffrey Jefferson Brain Research Centre support staff (support agreed) as soon as confirmation of funding is received, even before the start of the project. As recruitment will only commence at month three of the project, we foresee that we will have been granted ethical approval by then for a project that essentially poses very limited risks to participants.*

**3. There is insufficient information on the onward costs if the trial is successful. How much does the actual app cost? What ongoing costs would it have if successful?**

*The exact onward costs of the use of the app are rather difficult to calculate as they are dependent on the chosen funding model, the number of users/patients utilising the app and whether the model uses an organisational monthly subscription or annual renewal. However, what can be said is that the cost of our current apps are governed by the NHS procurement framework which guide and regulate prices for services. This framework additionally assists the uptake, set-up and roll out of services.*

*A preferred income model for the app would be costed annually through a licencing model on a sliding scale based on annual patient volumes at each Trust (the main app users). Other income models will be considered, including risk share with cost savings (e.g., optimised resource use, reduced secondary-care admission, evidence-based cost-effective treatments) shared between MDSAS and NHS (inc. CCGs) at a 30:70 split. Optimal income models will be continually evaluated, and app costs will be finalised following post-pilot evaluation of app benefits. As the project will utilise the existing and proven MDSAS patient support app for which the IP is wholly owned by MDSAS, there are no constraints in our ability to re-purpose and utilise the app for this project. This will help greatly to simplify income models and procurement into NHS organisations.*

*The MDSAS team have over 25 years' experience of achieving successful implementation of our solutions nationally in NHS organisations. Experience has taught us that a lack of access to NHS institutions (and clinical leaders) at appropriate levels with influence on implementation and procurement is often a major barrier to adoption. Collaborating with our NHS Trust consortium partner and the Greater Manchester Integrated Stroke Delivery Network (who have influence on local budget holders) will enable us to overcome this barrier and to implement the app and pursue procurement and wider implementation at pace throughout Manchester Trusts. To support this, we will produce marketing materials demonstrating improvement to patient outcomes, improved resource efficiency and health economic benefit.*

*MDSAS has significant experience of commercialising systems throughout the NHS, working directly with NHS England, Public Health England, CCG's, Specialist Commissioning Regions, NHS Trusts and GP Practices. MDSAS systems have been purchased and are in use in over 160 NHS Trusts and GP Practices. To assist NHS organisations in the purchase of our solutions we are registered with key national NHS procurement frameworks including G-Cloud Digital Marketplace and Digital Outcomes & Specialists which enable faster and simpler procurement of our solutions.*

#### **4. Compatibility - How up to date does smartphone need to be? Does it work on android and apple?**

*The app is built with the latest progressive web app (PWA) technologies with patient and clinician portals that can be accessed from any device including smartphones to facilitate patient input or NHS computers for clinicians. The app does not require the newest smartphone technology and is compatible with phones that are up to 6 years old (i.e., iPhone 7).*

*As the app is developed and delivered as a web app it is compatible with any operating system (i.e. Apple and android). Web app technology also eases app installation as it can be installed from a weblink sent by text/email and does not require use of operating systems (e.g., App Store or Google Play).*

#### **5. Engagement - How are the stroke team being brought on board with this? Are they already signed up to it or is that yet to happen?**

*Stroke teams across Greater Manchester are already on board with this proposal as the application has been co-developed with PPI and clinical stakeholders (stroke teams). The stroke teams have been involved through the Greater Manchester Neurology and Integrated Stroke Delivery Network (GMNISDN). Involvement comprised of two meetings with up to 14 lead therapists from units across Manchester and two presentations of progress of app development.*

*The input from the stroke teams has been key in the design of the therapy platform, considerations what resources should be provided for the patients, the addition of a home exercise repository and the possibility to input personalised goals. The clinicians felt that one*

*of the key benefits of this app would be to improve information transfer from the acute therapy services to early supported discharge and community care. They perceived that a barrier for implementation is the accessibility of the app on local NHS computers and services. We will continue to work closely with the GMNISDN clinicians to address these barriers and optimise the benefits.*

**6. Is a target pop of 20 sufficient to develop the evidence base required?**

*The aim of this study is to establish the feasibility and acceptability of the app. The interviews will be conducted with a sample of individuals with varying experiences and engagement with the application. We acknowledge that 20 is a limited number of participants however, as these interviews will be in-depth and conducted by an experienced qualitative researcher, we believe that they will provide extensive insights of the main research aims. In addition, we will collect data of input frequency, length and completeness from all participants for three months and we foresee that these will be much larger number. In parallel work we are increasing the functionality of the app. We will update the application in-line with findings from the feasibility study and will apply for funding to roll out the application across Greater Manchester through collaboration with the Greater Manchester Neurology and Integrated Stroke Delivery Network to perform a robust evaluation.*