

Service Definition

G-Cloud 12 Framework

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TinyMedicalApps.

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1.0 Introduction

1.1 Company Overview

Tiny Medical Apps puts children and young people with long-term conditions in control of their health by engaging, activating and empowering them, through beautiful, accessible apps. We do this through the Digital Health Passport.

We develop mobile apps for NHS partners. We are partnering with leading UK based NHS user centred design companies with extensive experience working with young people. Patent facing apps that hold care plans and allow people to contribute data into their healthcare record is a priority in the NHS Long term plan. We believe the objectives of the NHS Long Term Plan and The Digital Health Passport our flagship product are well aligned.

We are ISO 27001 accredited and were founded in 2016 by Matt Bourne (NHS Systems Developer) and Dr Greg Burch (Emergency Medicine Doctor).

1.2 What we provide

Digital Health Passport

Our core service is a personal health record (PHR) app for children and young people with long term conditions called the Digital Health Passport which is being implemented within the NHS in London, Sheffield and Manchester and is supported by the NHS England Innovation and Technology Payment (ITP) Evidence Generation Fund for PHR.

The key features are a symptom diary, links to educational resources, a personalised condition emergency and action plan with alerts for pollution and pollen.

The app, which has been funded by Innovation and Technology Payments from NHS England and is being rolled out in Greater Manchester and South

Yorkshire, has functionality to support remote review and care planning in response to changes in workflow and capacity due to Covid-19.

Key parts of a condition review involve understanding the symptom history and medication use, checking skills and assessing knowledge and the ability to self-manage - these are all carried out by patients in advance.

Whilst initially focused on asthma the Digital Health Passport has additional support for allergies and is flexible to suit people of all ages and other conditions where patient engagement, activation and empowerment can help improve outcomes and make interactions with healthy professionals richer and more efficient.

We are working with NHS organisations of all scales to support additional long-term conditions in the Digital Health Passport utilizing existing functionality in our core product and adding additional features and customisation.

DHP Features

- Onboarding and screening module: safe app personalisation and user assessment.
- 2. Health tracker: Recording clinically validated patient focused and symptom measures
- 3. Health and Emergency Action Plan: clinician approved and shareable
- 4. Health Hacks: Health and wellbeing education resource videos and links
- 5. Air Quality, Pollution and weather alerts: Triggered by location services
- 6. Remote condition review: in advance medication use and health check
- 7. Training Modules: Structured content around condition reinforced by quiz questions
- 8. NHS App Library, Apple App Store, Google Play: Widely available
- 9. NHS and Social Login: Secure log in

10. Interoperable with LHCR, EMIS, System1 and other EHR's

DHP Benefits

User / Patient

- 1. Improving patient understanding and condition management
- 2. Supports patient self-management
- 3. Increases patient activation
- 4. Minimising face-to-face and unnecessary appointments (follow-up management)

Clinician

- 5. Improving facilitation of knowledge and training around condition management and medication use.
- 6. Enhancing quality and efficiency of consultations and reviews
- 7. Validated Behavior Change

Commissioner / System

- 8. Moves from paper based action plans and records to digital
- 9. Reduction of unplanned hospital attendance
- 10. Facilitates better population health management amongst children and young people

1.3 Evidence of Impact

Validated Behaviour Change

The provision of educational materials and an agreed self-management plan are core features of the Digital Health Passport, however in order to maximise the potential of the tool we are including validated behaviour change techniques and will test their effectiveness in a large RCT in east London in the coming years.

An analysis by Dr Samaresh Mazumdar and Dr Liz Edwards, under supervision of Prof Chris Griffiths and Dr Anna De Simoni of Queen Mary's University London identified the 14 BCT's in use in the app and

recommended further we could introduce based on analysis of 50 asthma apps used internationally. The current version incorporates and evaluates further BCTs based upon the recommendations from QMUL researchers, particularly with greater ability to contribute to the care plan from patients with regard to goal setting, action planning and thus increased status within the team.

Evidence for asthma plans and self-management education reducing hospital attendances

The evidence in favour of supported self-management for asthma is overwhelming. Self-management including provision of a written asthma action plan and supported by regular medical review, almost halves the risk of hospitalisation, significantly reduces emergency department attendances and unscheduled consultations, and improves markers of asthma control and quality of life (Pinnock, Breathe 2015).

The British Thoracic Society/Scottish Intercollegiate Guideline Network (BTS/SIGN) asthma guideline cites 261 randomised controlled trials reported in 22 systematic reviews in support of its grade A recommendation that "all people with asthma (and/or their parents or carers) should be offered self-management education which should include a written personalised asthma action plan and be supported by regular professional review"

1.4 DHP Product Overview

Onboarding and screening module

Users will be taken through a series of onboarding questions to customise the DHP by type of user, condition and locations; and screening questions to filter out inappropriate users, assess condition severity and signpost users who may need emergency intervention.

Health tracker

Collecting quantitative & qualitative patient focused measures - Not just recording peak flows, symptoms or clinically validated scores such as EQ-5D but days off school/sport due to asthma / allergy, feeling of stigma associated with inhaler / AAI use or bullying related to health condition. Examples are:

- Peak flows
- Asthma symptoms
- Allergy symptoms
- Symptom severity
- Day off work / school
- Medication Use
- Health Service Contact
- Mood
- Smoking
- Exercise

Health and emergency action plans

Asthma and Allergy Action Plans are either entered by a clinician where integration to a LHCR/Clinical Systems is available and the plan shared with the patients in app or plans are entered by the patients directly into the app and then validated by the clinician using a secure email review process.

- Green every day treatment
- Yellow step up plan
- Red emergency plan
- (Blue step down plan)

Emergency plans can be shared in app by users to third parties. The plan will be sent by email or text message as a weblink to a downloadable PDF.

Health Hacks - Education resource videos and links

Educational materials (eg training videos, links to external websites) will be displayed within a Health Hacks section as videos or links to sites. This content has been developed alongside the app with content from support organizations such as Asthma UK.

Air quality, pollen and weather change alerts

Location services, with user permission, are used to provide the latest air quality, pollen and weather forecasts for their area. Alerts can be set when high levels are predicted or weather warnings are issued.

Remote condition review

Key parts of an asthma and allergy review involve understanding the symptom history, checking correct medication use and technique and assessing knowledge and the ability to self-manage - these are all carried out by patients in advance of a review in app using alerts and a review module.

The review module alerts users to answer questions such as the Asthma Control Test and enables 'selfie' videos within the app to demonstrate inhaler technique.

Training module with learning quizzes

Structured training modules will be provided at onboarding and with follow up reminders for training at fixed intervals. Each module will feature learning content reinforced by a series of quiz questions.

Gamification

Following completion of health diary, training and review modules the app will display, as part of the home screen, reward badges and streaks.

Alerts and notifications based on user activity and location

Linked to the Health Plan and entries into the health tracker the app will, with permission, alert users to use features within the app such as the

health tracker to enter a peak flow diary or to take training modules. With user permission a location based notification will be displayed when leaving a set home location to remind the user to take their medication with them.

Patient authentication

The Digital Health Passport will register and authenticate users through NHS or Social Login. Users do not have to go through the process again - the app is secured using the phone's passcode or biometric features.

NHS Login, used to access NHS App, allows users to log into approved health apps and allows integration with Local Health Care Records across primary and secondary care.

Social login uses a single sign-on using login information from a network provider like Facebook or Google to register and login users to the DHP. This simplifies registration and login for end users and, in this use case, will help maximise adoption by CYP who may find NHS Login a barrier to use.

Patient consent

Patient consent obtained in line with GDPR for data sharing, geolocation and notifications.

User walkthroughs and support

Within the app there will be walkthroughs showing the features of the app and help screens to help patients if needed.

App analytics

Administrators will received a weekly email notification providing and update of the following data:

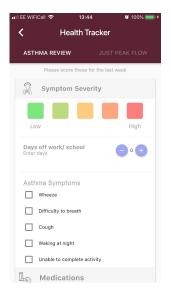
- Downloads
- Users numbers
- Active monthly users
- Training module activity

V1 Screen Shots

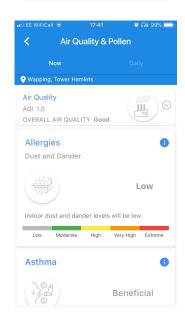












1.5 Associated Services

Integration / Interoperability

We are already work with LHCR Exemplars around the country (One London, Yorkshire & Humber and Greater Manchester) to integrate the DHP into local health care records. Within these areas new projects can be integrated as standard.

Working with trusted partners such as Black Pear Software and Coordinate My Care we are able to make bespoke integrations with a variety of clinical systems.

Co-design, Prototyping & Development

The Digital Health Passport is available as a standard product which can be deployed for Asthma and Allergy uses in any locality. We also are able to offer bespoke tailoring of the DHP to suit other long-term conditions and to support research and innovation projects.

2.0 Data Protection

2.1 Information Assurance

Security Governance Standards

The Digital Health Passport requires a high level of regulatory assurance. Significant effort has gone into delivering a safe and assured platform. Tiny Medical Apps has a dedicated board level Chief Technology Officer responsible for the security of all our services. We comply with the following governance / accreditations:

ISO/IEC 27001

ISO/IEC 27001 Information Security Management system is designed to help organisations manage their information security processes in line with international best practice

Our certification is externally audited by BSI and our scope specifically covers the Digital Health Passport platform.

Cyber Essentials +

Cyber Essentials helps us to guard against the most common cyber threats and demonstrates our commitment to cyber security. We are Cyber Essentials + certified which means we are also externally audited.

Clinical Safety DCB 0129, DCB 0160

These standards provide a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those health organisations that are responsible for the deployment, use, maintenance or decommissioning of Health IT Systems within the health and care environment.

NHS Apps Library

Gaining acceptance to the NHS Apps Library has been time consuming, but is a huge assurance hurdle that has been overcome. The bedrock of the process is the Digital Assessment Questionnaire (DAQ) which requires passing assurance in seven domains from clinical need, evidence to information governance and security.

NHS Login

The developers Tiny Medical Apps were invited to be in the first wave of companies allowed to use NHS login. We have invested in attaining all of the additional assurance requirements to enable rapid integration with regional Local Health & Care Records such as One London.

SCAL

The Supplier Conformance Assessment List (SCAL) is a technical document which details the consumer supplier approach to information governance, clinical safety, functional testing and SMSP-PDS requirements.

As part of our compliance and conformance assessment for NHS Login we successfully completed the requirements of the SCAL.

Information security policies and processes

Our security policy and processes are internally and externally ISMS ISO27001 auditor. We follow the Data Security and Protection Toolkit to provide assurance that we are practising good information security and that personal information is handled correctly.

2.2 Data Back-Up and Restoration

Tiny Medical Apps ensure that backup copies of switch configuration and data stored on the network are taken regularly in accordance with the Backup Policy and specific system requirements.

TMA ensure that a log is maintained of switch configuration and data backups detailing the date of backup and whether the backup was successful. Documented procedures for the backup process and storage of backup tapes shall be produced and communicated to all relevant staff. All backup tapes are stored securely and a copy stored off-site. Documented procedures for the safe and secure disposal of backup are produced and communicated to all relevant staff.

The restoration from a backup is tested regularly and the process documented; the restoration testing is carried out at least annually.

2.3 Business continuity plan

TMA has an active Business Continuity Plan that covers their IT systems to enable a structured recovery post an IT or information security incident.

This relates to the IT and information elements of the overall Tiny Medical Apps approach to Business Continuity. Business Continuity is defined as the capability of Tiny Medical Apps to continue delivery of products or services at acceptable predefined levels set with the service level agreement following a disruptive incident.

Tiny Medical Apps use the "Plan-Do-Check-Act" (PDCA) model to plan, establish, implement, operate, monitor, review, maintain and continually improve the effectiveness of its Business Continuity Plan for IT and information.

The Business Continuity Plan enables immediate responses to be made to an information security incident (IT or information). The Plan is regularly tested, and reviewed annually. The plan identifies key roles and responsibilities for which all office holders undertake specific training.

A more detailed plan can be provided to buyer on request

3.0 Using the service

3.1 Ordering and Invoicing

To access the service potential customers should email our Strategic Partner Manager using the contact email on the Digital Marketplace. TMA will send a use case questionnaire to understand your requirements and suitability for the service. We then arrange a remote meeting to confirm your requirements and assist in completing the G-Cloud order form / call-off contract.

Invoicing is as per our standard terms and conditions

3.2 Availability of Trial Service

The Digital Health Passport is available to download from the Apple App Store and Google Play. The free version does not have interoperability with

clinical systems or care plans but does show the range of functionality including pollution and weather alerts, health hacks and health tracker.

On request we can provide prospecting customers with a staging user account to view full features of the app.

3.3 On-Boarding, Off-Boarding, Service Migration, Scope etc.

Onboarding

We provide 1-on-1 web based training and support on the DHP platform for clinical sponsor and clinical champion and develop onboarding based on our standard workflow for the wider service.

The standard plan has these headings:

- 1. Welcome Pack
- 2. Clinical Safety Workshop
- 3. Information Governance Workflow
- 4. Deployment Plan
- 5. Reporting Schedule

Clinical sponsor and clinical champion will be assigned a single point of contact within Tiny Medical Apps.

Off-boarding

On receipt of termination request we will notify the project sponsor, clinical sponsor and clinical champion by email of the service end date and confirming that access and support will be withdrawn.

Users of the app will be notified in app that the NHS supported features are to be terminated and can request to extract their data in line with GDPR in a portable format.

Once the contract has ended unsupported app users will be logged out of NHS login and will be able to login using social login. Their data will still be

accessible and users will no longer have access to NHS supported features within the app.

3.4 Training

Typically we run an online webinar training session for the project sponsor, clinical sponsor and clinical champion which is recorded to be made available to other team members. Links to documentation, how to's and support are provided and linked during this session.

Patient Users are onboarded in app through an interactive module. Help, how to's and support are accessed within the app.

3.5 Implementation Plan

A detailed implementation plan can be provided to the buyer on request

3.6 Service Management

Our overall high quality approach is underpinned by our ISO 27001 certification. This means that we are internally and externally audited to ensure compliance with our Standard Operating Procedures which includes Information Confidentiality, Integrity and Availability.

Our ISO 27001 accredited Information Security Management System also includes a Business Continuity Procedure and Business Continuity Plans / Disaster Recovery in which several key scenarios are tested. The general approach is Step 1: initial Response (Containment) / Step 2: Continuity (Recovery).

Where we identify issues that need resolving they are added to our JIRA CAPA Log (Corrective Action / Preventive Action) which forms a key part of our Risk Management System.

We also use an online Helpdesk Ticket Management System. These can be triaged onto the JIRA system as required - including the Incident Log which triggers the Incident SOP.

3.7 Service Levels & Constraints

Service Level Agreements are discussed and agreed prior to an order being placed and documented in the order form.

User Support

User support is available by email and ticketed webchat support between 9am - 5pm (UK time) Monday to Friday. Incoming messages from users are responded to within one (1) business day.

Availability of service

Our service level agreement available covers availability of the service.

A "Downtime Period" means a period of 120 consecutive seconds of Downtime. Intermittent Downtime for a period of less than 120 consecutive seconds will not be counted towards any Downtime Periods.

A Financial Credit is available where in a given calendar month service availability falls between

- 1. 99% and 99.99% at 10% of monthly service costs.
- 2. Below 99% at 25% of monthly service costs.

Notification

In order to receive any of the Financial Credits described above, Customer must notify Tiny Medical Apps support within thirty (30) days from the time Customer becomes eligible to receive a Financial Credit.

Maximum Financial Credit

The aggregate maximum number of Financial Credits to be issued will not exceed 50% of the amount due from the Customer for the Covered Service for the applicable month. Financial Credits will be made in the form of a monetary credit applied to future use of the Covered Service and will be applied within sixty (60) days after the Financial Credit was requested.

Exclusions

The SLA does not apply to any features designated Alpha or Beta (unless otherwise stated in the associated Contract).

3.9 Outage and Maintenance Management

When an estimated prolonged outrage is detected we will communicate directly via an email alert to our customers with details of downtime and when the issue is resolved. This is documented in our Service Level Agreement standard operating procedure available on request.

4.0 Provision of the service

4.1 Customer Responsibilities

Project Resourcing

Customers will need to nominate appropriately skilled personnel for the implementation / deployment of the Digital Health Passport within their organisation. As a minimum TMA recommend the identification of a project sponsor, clinical sponsor and clinical champion. TMA are able to provide additional support in this respect as a consultancy service as required.

Clinical Risk Management

Compliance with DCB0160 (Clinical Risk Management) will be assessed and arranged locally by the customer as required. TMA has complete internal reviews to comply with DCB0129 which will assist the customer in the development of documentation and help facilitate clinician safety workshops as required. TMA are able to provide additional support in this respect as a consultancy service as required.

Information Governance

The customer is responsible for ensuring that their use case for the Digital Health Passport conforms their organisations Information Governance Policy. TMA are able to provide additional support in this respect as a consultancy service as required.

4.2 Technical Requirements and Client-Side Requirements

The Digital Health Passport can be used as a stand alone service without integration with clinical systems using NHS email and modern web browsers.

In order to gain the maximum impact and functionality for patients, clinicians and commissioners the DHP can be integrated into a range of electronic health records and clinical systems depending on the customer's region and use case.

We are able to provide details of current and future interoperability on request and provide an integration service where not available.

4.4 Development life cycle of the solution

Internally we use Agile methodology to ensure effective delivery of constantly improving software. Our developers are given training in Agile as part of their induction. We use JIRA to manage Sprints, Backlogs and Reviews. We prefer to share the Product Owner role between an in-house employee and a nominated client employee. Our CTO manages the Scrum Master and works with the Product Owners to ensure we can keep in line with the more static milestones within our product development roadmap.

4.5 After-sales Account Management

An estimated 80 percent of technology projects in healthcare fail to be implemented successfully. There are a number of reasons for this that are generally well understood. Key is the importance of the relationship

between the customer and the software supplier and the ongoing involvement of users - the citizen patients.

We use a number of tools and approaches to help navigate this journey; ensure high quality customer service and be able to react to a constantly changing environment.

Our overall approach is guided by the groundbreaking work of Prof Trisha Greenhalgh: NASSS Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies.

This allows us to contextualise our solution within an understanding that Personal Health Records from the perspective of providers (digital-first services), suppliers (interoperability) and consumers (accessibility / engagement / activation) are on a journey from complexity to simplicity. We use the NASSS to score at the beginning of the project and every 6 months.

4.6 Termination Process

Customer contact will notify TMA Strategic Partner Manager with a request to terminate the contract. Please refer to our standard service terms and conditions.

5.0 Our Experience

5.1 Case Studies

East London: Healthy London Partnership / Tower Hamlets CCG / Barts Health NHS Trust

TMA was commissioned by Healthy London Partnership to deliver a platform and app that would allow: deployment of digital care plans; remote condition monitoring; access to educational resources for young

people with long term conditions; and have access to pollution, pollen and weather data.

The initial focus was on asthma, and involved working with leading clinicians and young people across the capital to develop our 'Minimum Lovable Product'. The DHP was initially launched in October 2019 at two sites in East London: Chrisp Street Surgery and the Royal London Hospitals with Barts Hospital following on in January 2020. An evaluation has been undertaken demonstrating evidence to Tier 2 on the NICE Evidence Standards Framework for Digital Health Tools and presented to clinicians and commissioners from across London. The 'live co-design' continues supporting Respiratory Nurses at the Royal London to provide a Digital Asthma Action Plan to patients preparing for discharge.

Within the patient group those onboarded were positive about the app with a high number being active users of the care plan and remote condition monitoring features. One user summed this up: "The name as a Digital Health Passport is exactly it – you can travel around with it and use it as and when you enter into a service." We received concrete user feedback for future features, which will lead to us registering the DHP as a medical device.

Clinicians were highly supportive of the key features – allowing patients access to their care plans at all times on their smartphone was highly prized with one commenting: "This app is just brilliant and could save a life".

The main challenge during the pilot was recruitment of teenage users – this included a lack of appointments for care plan reviews and high level of 'Do not attends'. The need for an additional 'Clinician Portal' for healthcare professionals to enter care plans into was also a significant barrier to adoption at scale. Ideally care plans would be entered into native GP or hospital software and a Personal Health Record app (PHR) would 'pull' the plan via a Local Health & Care Record. Using another portal requires changes to workflow, potential double entry and additional technology to be incorporated within already constrained consultation time.

The pilot, with the support of the clinical teams, allowed us to have a presence within clinics, enabling us to gather evidence and feedback whilst providing support and encouragement for the clinicians and patients – critical for adoption at this stage. The evidence and learnings generated from the pilot are centered around how it is possible to concentrate on patient adoption through the PHR app and for the clinician involvement to form part of existing and developing clinical systems. In addition the pilot has highlighted issues around interoperability between PHR's and Electronic Health Records (EHR).

Manchester: Greater Manchester Health & Social Care Partnership

The Digital Health Passport team was approached by the Greater Manchester Strategic Clinical Network. This followed an extensive piece of research into the needs of children and young people in their area which identified an asthma care plan app as an important part of a strategy to reduce Emergency Department visits.

The Greater Manchester project has received £100k Evidence Generation funding from the Innovation & Technology Payment, an NHS England programme that supports the NHS to adopt innovations by removing some of the financial and procurement barriers to introducing new technologies, and is well supported by the regional leadership team and the local Academic and Health Science Network.

The integration plan with the GM Local Health & Care Record (LHCR) is amongst the most advanced in the country and involves evaluating the use of PODs (Personally Owned Datastores).

The focus for the project is to share asthma care plans between secondary and primary care, and once interoperability is established to do the same for epilepsy and diabetes.

Key deliverables

- Connect to Greater Manchester Local Health Care Record using NHS login
- Customise the Digital Health Passport to the local environment
- Demonstrate evidence of improved Patient Activation Measures in young asthmatic population
- Demonstrate evidence of Tier 3 of NICE Digital Health Tools framework

Sheffield: Sheffield Children's Hospital NHS Foundation Trust

Sheffield Children's Hospital in association with National Institute for Health Research (NIHR) Children and Young People MedTech Cooperative have been awarded £67k Evidence Generation funding from the Innovation & Technology Payment, an NHS England programme that supports the NHS to adopt innovations by removing some of the financial and procurement barriers to introducing new technologies, to integrate the Digital Health Passport with the Yorkshire & Humber Care Record, a Local Health Care Record Exemplar.

This project focuses on allergy/anaphylaxis care plans and working with community clinics to reduce out patient appointments and urgent care demand.

Current paper processes result in children with asthma and severe allergies having 2 separate care plans which is far from ideal in an emergency. Co-design work will integrate the care plans and take them to national groups for approval.

Key deliverables

- Connect to Yorkshire & Humber Care Record using NHS login
- Develop allergy/anaphylaxis care plans that integrate with asthma care plans
- Customise the Digital Health Passport to the local environment

• Demonstrate evidence of improved Patient Activation Measures in young population with allergies

5.2 Clients & Partners







Greater Manchester and Eastern Cheshire Strategic Clinical Networks





Healthy London Partnership











5.3 Contacts & Team

Our Team

Matt Bourne Chief Technology Officer

Greg Burch Clinical Director

Vipin Kashyap Development Lead

Catherine Beverley Team Coordinator, Product Owner for DHP

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