

System Integration – Transformation Business Analysis

Project / Programme: Dorset ICS Remote Monitoring &
Remote Management Supplier SaaS
Procurement

Document: Remote Monitoring & Remote
Management Business Requirements

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Document History

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V00.1	24/08/2023	First draft issued for initial review by Carol Joseph and Samuel Howard
V00.2	26/09/2023	Second draft for initial review by Stephen Slough
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Document Review and Approval

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Enterprise Architecture Steering Group	NHS Dorset	
D@SH (Digital Access to Services at Home)	NHS Dorset	

Distribution *(Informed)*

Name	Organisation / Department
[Recipient Name]	[Organisation]

Supporting Documentation

ID	Description	Document (actual copy or link)
Appendix 1.	Virtual Wards Enabled by Technology – Guidance on selecting and procuring a technology platform	
Appendix 2.	Virtual ward and remote monitoring specific • NHS England Virtual ward resources • NHS England Guide to setting up a virtual ward • NHS England Guide to setting up technology-enabled virtual wards • NHS Blueprint: Remote monitoring of COVID-19 patients using cloud-based digital solution – primary care (escalated care clinic) and secondary care Guidance for digital technologies • DTAC • DCB0129: Clinical Risk Management: its Application in Manufacture of Health IT Systems - NHS Digital • DCB0160: Clinical Risk Management: its Application in Deployment and Use of Health IT Systems - NHS Digital • Health App Assessment Criteria • MHRA device regulations (software applications guidance) • NHS England Architecture principles • Best practice guidance for data-driven and healthcare technologies • Government Design principles • Evidence standards framework (ESF) for digital health technologies Our programmes What we do About NICE • HFMA Digital technology resources map • Digital clinical safety strategy Data and interoperability • Data saves lives • Interoperability Standards (Draft) Procurement • Procurement framework strategy recommendations • NHS service standard	Strategic Operational releases, contract 23/24

Appendix 3.	Remote Monitoring Partner – To Be pdf	
Appendix 4.	Brief with Workforce & Patient Scenarios – PowerPoint slides	

DRAFT

Lexicon and Acronyms (AKA Glossary)

Any references to processes, systems, organisations groups, acronyms etc, contained within this document are included in the table below with an explanation of each:

Item	Description / Explanation
API	application programming interface
EPR	Electronic Patient Record
FHIR	fast health interoperability resources
HIE	health integration engine
IHE	Integrating the Healthcare Enterprise
HL7	Health Level Seven or HL7 refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers
LHCRE	local health and care record exemplar
MHRA	Medicines and Healthcare products Regulatory Agency
PDS	Patient Demographic Service
PREMS	patient reported experience measures
PROMs	patient reported outcome measures
SNOMED	SNOMED CT is a structured clinical vocabulary for use in an electronic health record. It is the most comprehensive and precise clinical health terminology product in the world
SaMD	Software as a medical device
SaaS	Software as a service
SOFTWARE	Software as a set of computer programs and associated documentation and data
DASHBOARD	Dashboard in this document refers to an administrative, clinical or patient graphical user interface. This is inclusive of (but not limited to): • At-a-glance views of key performance indicators relevant to a particular objective. • Lets users view, input and manage personal data collected for clinical and operational requirements.

Executive Summary

NHS Dorset have a strong approach to the design of digital, technology and data. The latest [Integrated Care Partnership \(ICP\) strategy](#) draws out a theme of Prevention and Early Help (Our Dorset Strategy, Prevention and early help, 2023). Our [Joint Forward Plan](#) published on 30th June 2023 refers to our digital plan on page 66 explaining that we will help our citizen access the information they need, when needed to take proactive steps in managing themselves. Dorset Digital leads will continue to work across the system to deliver our ICS digital framework as set out under [What Good Looks Like](#) in helping to understand our population needs through:

1. Integrated data sets and the intelligence and insights they provide in segmenting and risk stratifying our population
2. Use of digital health technologies in managing demand in a different way through new models of care which will help our population with self-monitoring and management,
3. The convergence of digital health and care records that can be shared in real-time between clinical and care settings enabling safer care
4. Use of AI and RPA in improving efficiencies in processes and enhancing productivity freeing up clinician time for patient-centred care
5. Ethical consideration and safety.

Integrated data sets for intelligence and insights

We understand [data saves lives](#) so we want to grow, curate and architect integrated and combined datasets from industry partners, health and care systems, police and fire for insights and analytics to plan services and to risk segment or stratify our population. The insights are used to help inform problems we need to solve or identify those in need particularly in areas of deprivation, and measuring the impact of innovation for investment and health outcome purposes.

Digital health technologies to manage demand in a different way.

Digital health technologies (DHT) for citizens to monitor their own health e.g., apps that help access to medical records, test results, appointment scheduling, prescription requests as well as tracking symptoms, analysing trends, keeping medication diaries that help screen conditions and inform diagnosis and management. These technologies can surface in a smartphone app, wearable device, and software that provide remote monitoring.

Convergence of digital records

In Dorset we have benefitted from the development and widespread use of a single view of health and some social care data through the Dorset Care Record for several years. It is considered to be one of the most mature and feature rich longitudinal care records in the country. It provides a practitioner with an excellent overview of the patient sat in front of them, allowing them to treat the whole person, not just the symptoms. However, our ambition takes us to a place where data and information can be freely shared between clinical and care settings that also allow for updates and new notes to be added across the health and care landscape. We have excellent alignment in Primary Care into Community Care already, with transformation programmes planned in Mental Health and Acute care settings, alongside a technical development to bring about a step change in our interoperability capabilities. Improving the use of data records will in turn drive an increase in the quality and detail of the data our applications hold. This richer data can then feed into our analytics capabilities and dramatically improve the quality of the insights we drive through research and studies.

Artificial Intelligence (AI) and Machine learning (ML) for improving efficiency.

Artificial Intelligence is going to be one of the great disruptors of health care, but it will take a while for our clinicians to build confidence. There is a growing need to find solutions to workforce shortages exacerbated by an ageing population with complex health and care needs. Such data collection and automation can be wrapped or surfaced in different applications such as robotic process automation and digital health technology. ML could aid the development of disease prediction models, software to improve diagnostic accuracy, treatment management enhancing patient care and clinical outcomes such as assisting health care professionals (HCPs) in anticipating and planning future patient needs.

Time spent on administrative processes can also be significantly reduced by using robotic process automation (RPA) to automate back-office tasks in the NHS. RPA has shown it increases operational capacity and speed and improves safety; it is available 24/7 and can undertake tasks 4–10 times faster with fewer errors.

Ethical consideration and safety

To improve our confidence in AI, we want to develop awareness and recognition of ethical considerations like fairness, transparency, and accountability supported by internal and external validation, and a robust evidence base with ongoing monitoring whilst complying with regulatory frameworks. This will also ensure operating environments are reliable, modern, secure, sustainable and resilient. We understand that compliance with UK law is not the same as a moral acceptance. Just because we can do something with data or technology does

not always mean we should or that it is the right thing to do and will look to adopt best practice of regulations and standards ([digital regulations](#)).

Such digital and data transformation requires consideration of implementation to the workforce in how developments such as artificial intelligence (AI), digital medicine and robotics are likely to change the roles of clinical and professional roles ([Topol, 2019](#)). Skills are needed in organisational development and project or programme management, digital clinical safety, and data literacy. Learning new technological skills is essential for digital transformation. But it is not enough we must be motivated to use these skills to create new opportunities. We need digital mindsets, and we recognise the need to address the support to the workforce at all levels as critical to design and implement change.

Such technologies as apps involving machine learning, robotic process automation and multicloud have been proven in research and case studies to help 1) reduce workload to clinical teams and burnout resulting in improved retention and reduced sickness, 2) empower the person or patient on their condition in a supportive self-management approach and 3) accelerate access to care for those that require it ([NIHR, 2022](#)).

Growing Digital Citizens with remote management and monitoring tools

Since 2017 Dorset has been developing its role as a leader or pioneer in digital citizen enablement to help ownership of health and help our fatigued and rapidly declining workforce. We have more than 8,000 patients utilising remote management options for COPD, Asthma, Heart Failure and Diabetes care, and a developing area of remote monitoring to enable virtual care models.

The multiple SaMD's have overlapping features and functions. This specification and requirements are to provide guidance and help us review the market to see if there a single software as a service (SaaS) that can wrap around our existing approach and help us develop the agenda further and faster.

To help bring the requirements to life we have developed scenarios to help the real world intended use.

SaMD's have an intended use of:

1) condition management – self-management. (stable and well patients)

These interventions are implemented predominantly in general practice with the support of community groups as part of early help. The registration is at mass as part of a marketing campaign or could be invite specific as part of an annual review. The intended use for this model is that the citizen/patient registers with the software and utilises the functions, features, educational content to help reduce variation in advice and guidance in managing ones condition and help understand triggers where they might deteriorate.

2) remote management - which is supported self-management (rising risk patients)

Building off self-management and again predominantly implemented in primary care with some community and acute aspects. Should the patient initiate a follow up or for use by clinical / professional team e.g:

- a) symptoms deteriorate
- b) hybrid models to deliver pulmonary or cardiac rehab

The software surfaces data capture for review to aid or replace care plans a follow up or as part of an annual review.

3) Remote monitoring - enable virtual care / wards (Higher risk patients)

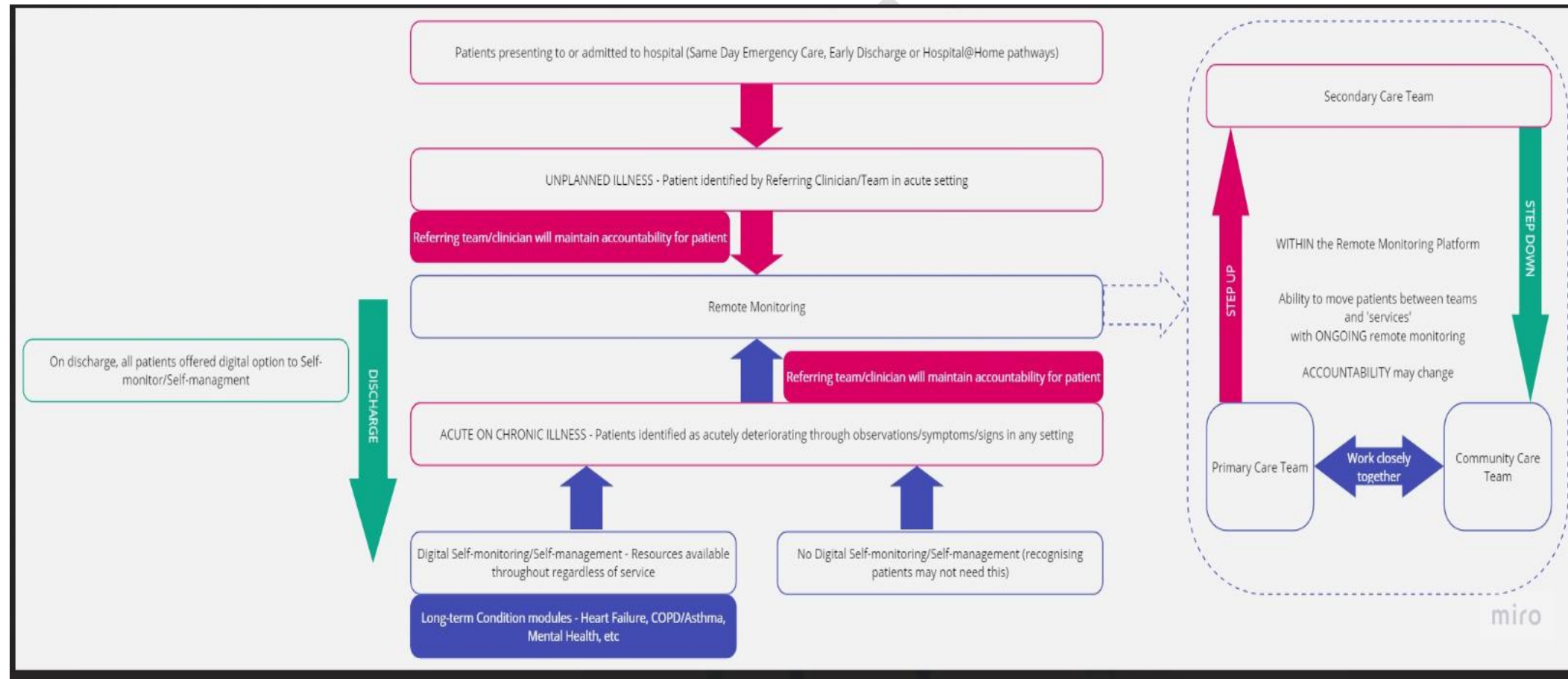
These are digitally higher risk patients and decisions / clinical accountability is usually led by the acute clinicians as part of a hospital admission avoidance or step down / transfer of care model. The vital signs of

NEWS2 and an oncology module are what inform the remote monitoring hub who lead remote management as part of a virtual care service model and this is with medical device hardware.

User Types

ID	Name	Descriptor
User type 1.	<i>Patients</i>	The people who access the services. Some organisations may call them “Patients”, some “individuals”, some “service users”. This may include those (e.g.: carers) who are inputting data on the patients behalf.
User type 2.	<i>Professionals</i>	A professional may be someone from a clinical or non-clinical background.
User type 3.	<i>System Administrators</i>	Administrators of the system, which may include those with no direct access to the day-to-day software, such as those from the NHS Dorset Digital Team.

Patient Flow Diagram



1 General Requirements

1.1 Provider Implementation Requirements

Ref	Requirement	Priority (MoSCoW)	Owner / Source
1.1.1	<u>Scaling across large geographies and populations</u> The Provider must supply the evidence that they have the knowledge, experience and capacity to implement similar solutions to this scale across large geographies and populations. Evidence of number of patients and professional users who have used the platform and the concurrent load capacity, and evidence of sufficient devices where applicable.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.2	<u>Approach to transformation and clinical engagement</u> Provider to supply an overview of their approach to transformation and clinical engagement.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.3	<u>Project Management</u> Provider to propose an implementation and payment plan for the service using PRINCE2 or Agile methodologies. All reporting and governance are expected to meet PRINCE2/Agile standards.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.4	<u>Proposed payment milestones</u> Implementation plan aligns to the proposed payment milestones against the Provider proposal.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.5	<u>Change control procedure</u> Provider is to supply details around its contractual change control procedure and provide its SLAs for any change requests/product development requests.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.6	<u>Software implementation</u> Live, test, and training versions of system to be provided Test and training systems to obfuscate data / use dummy data	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.7	<u>Evolution with pathways</u> Flexibility to configure solutions as pathways evolve, based on an agreement about costs that are based on whether the functionality is scalable or is provider specific.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.8	<u>System Configuration</u> Provider to supply details of what is configured within the system for initial setup for NHS Dorset and what is not configured i.e. -configuration of workflows -views -e-forms -Document templates	Must	Graham Sheppard, Crystal Dennis, Alex Tealdi, Carly Ings
1.1.9	<u>Data Migration Strategy</u> Provision of data migration strategy for migrating selected data from decommissioned databases	Must	Graham Sheppard, Crystal Dennis, Alex Tealdi, Carly Ings
1.1.10	<u>System Implementation Testing</u>	Must	Crystal Dennis, Alex Tealdi, Carly Ings

	Provision of testing strategy for the system implementation completion of system application set-up, configuration and data testing that meets agreed user and system acceptance testing quality criteria		
1.1.11	Training Material and Courses Provision of training courses and materials for -system administrators -Advanced system users end users -permission to create local bespoke guides-	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.12	Training across multiple formats Ability for professional user training to be available in multiple formats including mobile, browser and face-to-face. Ideally this includes remote 1:1 training. A list of currently available training materials is expected to be provided. Should have: E-learning platform. Role based access based on training: Should (if eLearning portal could, otherwise should) Human resource to be provided for training - joined up approach between product and how it is then used.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.1.13	Training across the workforce Ability for professional user training to be available in multiple formats including mobile, browser and face-to-face. Ideally this includes remote 1:1 training. A list of currently available training materials is expected to be provided.	Must	Crystal Dennis, Alex Tealdi, Carly Ings

1.2 Provider Service Support

Ref	Requirement	Priority (MoSCoW)	Owner / Source
1.2.1	Service - The solution must have an associated Service Level Agreement in place that specifies performance guarantees, response times, supportability, and resolution times for issues - to be defined DTAC D1.11 to D1.12.2	Must	
1.2.2	<u>Evidencing quick responsiveness</u> Provider should evidence they can respond quickly to support requests, including prioritising those that are more clinically urgent. Evidence includes number of professional users that could be concurrently supported. This would be defined in a service-level agreement and monitored with key performance indicators.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.2.3	<u>End-to-end service</u> Provider to provide an end-to-end service for the duration of the contract. This is inclusive of standard ITIL disciplines such as change, release, incident, problem and event management.	Must	

1.2.4	<u>Agile and responsive working</u> Provider should evidence its ability to work according to agile principles and be able to cope with the changing needs of users, residents, providers and commissioners. Ability to quickly resolve bugs and errors and meet deadlines and requirements	Must	
1.2.5	<u>Service Review</u> A service review document is expected monthly. The content of the service review is agreed with the provider prior to service commencement.	Must	
1.2.6	<u>Quarterly improvement plan</u> A continuous improvement plan is expected on a quarterly basis. The content of the continuous improvement plan is agreed with the provider prior to service commencement.	Must	
1.2.7	<u>User insight informs development</u> Ability for the Provider to gain user insight/experience of the service and use this to inform its continuous development and how this happens.	Must	
1.2.8	<u>Service usage reporting</u> Ability to support usage analysis, which can be updated on an ad-hoc, weekly, monthly and annual basis. These reports should be accessible to NHS Dorset within the administration tools and customisable according to data informed benefit plans	Must	
1.2.9	<u>Continuous system monitoring and daily management</u> Software is to be monitored 24/7/365 by the Provider and managed within the hours of ???	Must	
1.2.10	<u>Out of hours, on-call service and service desk</u> Provider is to provide an out of hours and on-call service as well as service desk provision within business hours.	Must	
1.2.11	<u>Upgrades included</u> All upgrades are to be included with the software/platform and implemented by the Provider.	Must	
1.2.12	<u>No downtime during upgrade implementation</u> All upgrades are to be implemented with minimal downtime. The environment is to be warranted and maintained to all vendor best practice during the life of the agreement. Not to compromise the 99.9%	Must	
1.2.13	<u>FOI/subject access requests</u> Where appropriate, the Provider is expected to meet the NHS statutory requirements for Freedom of Information and Subject Access Requests.	Must	
1.2.14	<u>Service desk provision</u>	Must	

	A regional service desk provision for first- and second-line support for health providers is to be provided. Support is expected to be available to clinicians 24/7/365.		
1.2.15	Complaint Management Ability to record and monitor the progress of Complaints and Compliments There shall be a complaints management solution, where we can: - Record formal complaints - Attach actions and outcomes to user records (especially patient). - Record compliments and other feedback		Crystal Dennis, Alex Tealdi, Carly Ings
1.2.16	Ability to manage and comply with Subject Access Requests There shall be a subject access request view, where we can: - See all Subject Access Requests that have been raised. - Track progress of associated tasks, including information sent to users and what has/hasn't been redacted - Find, select and redact confidential elements of records / documents before copies are sent out in response to a Subject Access Request. - Print redacted versions of records / documents, clearly showing what elements have been redacted.	Must	
1.2.17	<u>Resolving P1/P2 incident</u> SLA doc P1/P2 incident what are your resolution timelines	Must	
1.2.18	<u>Unscheduled downtime</u> Any unscheduled downtime over and above the SLA may result in service credits	Must	
1.2.19	Environment upgrade Environment is to be continually patched and upgraded to the latest operating system and security standards. No unwarranted hosting environment or equipment will be tolerated. No out of manufactured support software may be used as part of the solution.	Must	
1.2.20	Wearable Devices Solution provider to provide wearable medical devices, which are compliant with regulations as part of the contract.	Could	
1.2.21	Updated training materials All training materials are expected to be updated for the duration of the contract and provided to the customer free of charge.	Must	
1.2.22	Support for end users Appropriate forms of technical support are available to patients and carers, including on-boarding support.	Should	
1.2.23	defined product roadmap and strategy in place for all system components Published product development roadmap	Must	

	rolling 12-18months and strategy in place for all system components including: -Current core functionality -Planned Core functionality -Optional Modules -Bespoke development		
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1.3 Provider Profile

Ref	Requirement	Priority (MoSCoW)	Owner / Source
1.3.1	Evidence of success and validation Evidence of Provider success and appropriate use cases. Provider ability to establish meetings between the purchaser and reference sites for validation.	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.3.2	Provider Profile – competency The solution Provider shall evidence and provide assurance on the competency of the MedTech team including IG, Clinical assurance, digital clinical safety, project management, product development and data science.	Must	
1.3.3	Provider profile - equalities		
1.3.4	Provider profile - Market leadership The Provider shall evidence to NHS Dorset in what ways it is a market leader in Remote Monitoring and Long Term Condition Management Software.	Must	
1.3.5	Provider profile - established in NHS / Healthcare setting The Provider shall evidence to NHS Dorset examples of where it has already provided both Remote Monitoring and Long Term Condition Management Solutions to Healthcare providers (ideally, NHS).	Must	
1.3.6	Provider / Solution Cost The solution cost shall not exceed X	Must	
1.3.7	The provider shall evidence positioning in the MedTech SaMD macro ecosystem and collaborative partnerships with other EPR, DPR and SaMD or SiMD for market development	Must	

1.4 Adaptability requirements

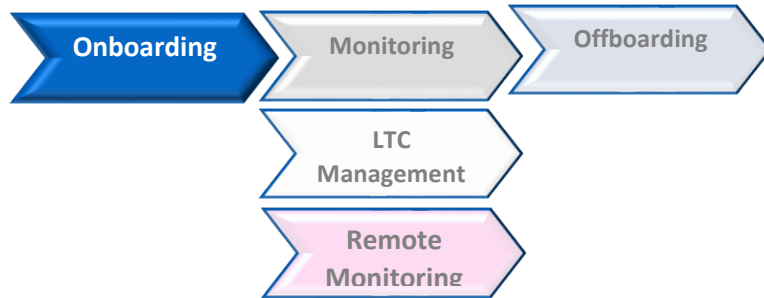
Ref	Requirement	Priority (MoSCoW)	Owner / Source
1.4.1	The Provider shall enable software for the following conditions (at minimum) to be in-scope for go live Long Term Condition management: - COPD (Respiratory), including pulmonary rehab - Asthma (Respiratory), - Heart failure (Cardiology) including cardiac rehab - Hypertension - Diabetes types2 (Must), including diabetes structured education	Must	Crystal Dennis, Alex Tealdi, Carly Ings
1.4.2	The provider will work with Dorset on a Mental Health Module to be developed within 24 months of the contract. This shall be co-designed between the solution provider and Dorset ICS.	Must	

1.4.3	The Provider shall enable the following software module (at minimum) to be in scope for Remote Monitoring: - NEWS2 Remote Monitoring service / pathway	Must	
1.4.4	The Provider shall enable the following condition to be in scope for the software for Remote Monitoring: - Oncology service / pathway Within 12months of go live of NEWS2	Should	
1.4.5	The Provider shall enable the following condition to be in scope for Remote Monitoring within 12months of initial NEWS2 go live: - Cardiology service / pathway	Could	
1.4.6	The software shall provide the capability for clinical users to monitor patients across all and any acuity levels.	Should	
1.4.7	The Provider will ensure the software shall be adaptable to meet our future Remote Monitoring Service needs, meaning that new services are able to be met by the solution as they emerge & develop. We would expect this to be achieved by the solution allowing specifically nominated super-users and clinical groups to be able to adapt / create new pathway variations for the remote monitoring solution based on clinical or system priorities. This includes but is not limited to the ability to modify functionality around content, questions, clinical data to request from a patient, data display, alerting, clinical thresholds, reporting and communication.	Must	
1.4.8	The Provider shall employ a qualified Clinical Safety Officer, who is supported by a clinical Team to provide NICE clinically updated content and best practice updates to modules in the software that are live for an updated DCB0129	Must	
1.4.9	The Provider shall design and provide all Long Term Condition Management and Remote Monitoring Condition specific clinical content for the RM platforms. This shall be for any conditions where Long Term Condition management is provided. This content shall be kept updated in accordance with NICE guidelines, although NHS Dorset will have the opportunity to review content updates before they are made, and choose to override the update should they choose to. In this instance, the Provider shall ensure a record of these decisions are kept logged. The updates the Provider makes to content in the duration of the contract shall be made at no additional cost to NHS Dorset.	Must	

2 Functional Requirements

These Requirements are Structured by the workflow steps which are enabled by the software. The requirements are for the software, rather than our NHS Service, but the structure helps to theme these requirements based on how the software will be used in practice.

2.1 Step 1: Onboarding Requirements



There are three sub-components to this process which are:

- 1) Patient Invitation
- 2) Patient Registration
- 3) Patient Activation

Patients are referred into the software differently, depending on which cohort they are a part of.

1. Generic Referral process.

We will use this process for patients who require Long Term Condition Management

2. Invite-only Referrals

We will use this process for patients who require Remote Monitoring.

There are 3 levels of Service which we would like to provide to our patients in Dorset:

- 1) condition management which is self-management.

This is predominantly carried out in general practice with the support of community groups as part of prevention. The registration is at mass or

could be invite dependent on the opportunity for discussion between the clinician / professional team and the citizen/patient. The intended use for this model is that the citizen/patient registers with the software and utilises the functions, features, educational content to help manage their own condition and help understand triggers where they might deteriorate.

The patient data is available to the clinical and professional teams but is not viewed until a citizen/patient initiates a follow up or as part of an annual review.

2) remote management - which is supported self management (replace early deterioration)

This is predominantly carried out in general practice by the condition speciality leads under consultation and advice from GP's or secondary care where appropriate. This commences when a citizen / patient initiates a follow up due to deterioration identified in their normal routine. It is part of anticipatory care and urgent community response work. The data is reviewed to help proactively advise on care to the citizen/ patient. This is not checked overnight or as part of a remote monitoring model of care but as de-escalation of risk.

3) remote monitoring to enable virtual care / wards.

These are digitally higher risk patients and decisions / clinical accountability is usually led by the acute clinicians as part of a hospital admission avoidance or step down / transfer of care model. The vital signs of NEW's2 are what inform this service model.

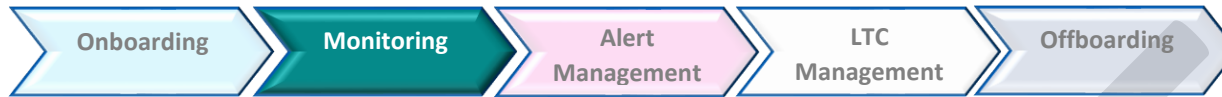
ID	Requirement	Rationale	User type(s)	MoSCoW	Owner									
2.1.1	Modular pathways There shall be a modular approach to the software which allows NHS Dorset to create specific modules, and corresponding access permissions for these.	So that it is easy to find the correct module that is relevant to the patient.	Professional RM Team Patients	Must	Keith Gomes Pinto, Crystal Dennis, Liz Tate, Cheryl O'Sullivan									
2.1.2	Patient access and referral-in Methods There shall be 2 methods enabled for a patient to be referred into / to access the software: <table><tr><td></td><td>Name</td><td>Description</td></tr><tr><td>1</td><td>Generic</td><td>To be used when patients can sign themselves up to the software, without needing to be invited.</td></tr><tr><td>2</td><td>Invite-only</td><td>To be used when we (NHS Dorset) have a service which we want to restrict from access by patients unless they are specifically invited.</td></tr></table>		Name	Description	1	Generic	To be used when patients can sign themselves up to the software, without needing to be invited.	2	Invite-only	To be used when we (NHS Dorset) have a service which we want to restrict from access by patients unless they are specifically invited.	So that if the patient needs parts of the software we would like to restrict, then method 2 shall be enabled. Otherwise, we use method 1 (generic) which puts as few barriers to entry for patients in place as possible.	Patients Professionals	Must	Crystal Dennis
	Name	Description												
1	Generic	To be used when patients can sign themselves up to the software, without needing to be invited.												
2	Invite-only	To be used when we (NHS Dorset) have a service which we want to restrict from access by patients unless they are specifically invited.												
Generic Referrals														
2.1.3	Generic Sign-up Method: QR Codes / links The provider shall create external URL access for patient registration which is linked to each GP practice (or if not possible to do this practice specific URL, a universal URL). These URLs shall enable a patient to sign up to modules which are not restricted in access.		Patients Professionals System Administrators	Must	Crystal Dennis, Alex Tealdi, Carly Ings									
2.1.3.1	Generic Sign-up Method: Personalising links As part of the professional RM dashboard functionality, the links shall be able to be made specific by any clinicians, professionals, and system administrators to: - A specific GP practices. - A PCN (Primary Care Network) - A Long-Term Condition type		Professionals System Administrators	Should	Crystal Dennis, Alex Tealdi, Carly Ings									
Invite only Referrals														
2.1.4	Invite only – Restricting access.		Patients Professionals	Must	Crystal Dennis, Alex Tealdi, Carly Ings									

	The Software shall enable NHS Dorset to create modules which can only be accessed by patients if they are specifically invited in by a professional.				
Generic Requirements for Onboarding					
2.1.5	Patients shall be able to sign up to the software via their NHS login.	So that the identity of the patient is assured, as well as having a simple sign up process for patients.	Patient	Should	Crystal Dennis, Alex Tealdi, Carly Ings
2.1.5.1	Spine verification As a result of a patient being signed up, the software shall pull the following information about the patient via a Spine Integration: • First Name • Surname • Date of Birth • Address • Patient Contact Telephone Number • Patient NHS Number		Patient	Must	Crystal Dennis, Alex Tealdi, Carly Ings
2.1.5.2	NHS SPINE (PDS) verification When a patient submits their sign-up form, this shall prompt the provider using the Spine to verify these details. The NHS login shall verify the information in real time (expected less than 10 seconds), and return a decision of whether the patient has been verified.		Patients System Administrators	Must	Crystal Dennis, Alex Tealdi, Carly Ings
2.1.6	Verification follow up actions. The following actions shall be taken by the software, depending on the response of the NHS login (Including Patient Demographic Service / SPINE). • <u>Patient Verified</u>: Software shall grant the patient access to the software, sending any relevant Communications to the patient to confirm this. • <u>Patient Not Verified</u>: Software shall send an error email to the email address of the relevant service / GP practice, with the relevant patient information.		Patients Clinicians System Administrators Professionals	Must	

2.1.7	Look up Patient by NHS number. Professional users shall be able to register patients to the software, with the software securely selecting and registering patients using the NHS Digital Personal Demographics Service (PDS) look-up capability to guarantee effective use of the NHS number.	This should be done to avoid the Shared Care Record having to utilise the PDS.	Professional RM Team	Must	Keith Gomes Pinto, Graham Sheppard, Paddy Baker
2.1.8	Minimal demographic data to lookup Any patients without an NHS number shall be traced by registering a minimal set of demographic data. Safety measures shall be built in with NHS Dorset to ensure at least 3 data points are captured (eg: Name, Date of Birth and Address).	So that minimal patient data is used to maximum effect in securely registering a patient.	Professional RM Team	Must	Graham Sheppard, Paddy Baker
2.1.9	Real time registration Registration shall take place in near real-time and not in batches.	When a patient is registered in real time, this means that the patient can start using the Remote Monitoring Technology straight away (eg: the same day) rather than relying on (for example) an overnight batch registration which means the patient cannot begin using the service until the next day.	Professional RM Team	Must	Crystal Dennis
2.1.10	Multiple Modules the software shall enable users - patients to access multiple condition modules, as long as their access permissions allows this. For example, if a patient has a Long Term Condition requiring Remote Management, but also needs Virtual Ward Remote Monitoring, the platform shall enable the patient to be onboarded to both services.	So that patients who have complex or a variety of needs can use the software to its full potential. For example, if they have COPD and Asthma, they should be able to access both modules.	Professional RM Team Patients	Must	Keith Gomes Pinto, Crystal Dennis, Liz Tate, Cheryl O'Sullivan
2.1.11	Distinct Views based on access. The Patient RM dashboard shall present Tailored information base of the patient's condition and needs (e.g., cardiac patients get cardiac information; diabetes patients get diabetes information).	So that based on the patient condition(s) they are shown signposting and questions / monitoring / Targeted advice and resources to support them in self-management and increase health literacy.	Patient	Should	Alex Tealdi, Carly Ings

2.1.12	Specific Access restrictions to modules Professionals shall be able to limit the access to modules by patients on a case-by-case basis.	For example, if the clinician feels a patient with COPD and Diabetes needs to focus on their Diabetes management, they can turn off the COPD module access for that patient.	Professionals Patients	Should	Crystal Dennis
2.1.13	Onboarding communication The software will provide in app communications via notification updates or nudges (automated or bespoke) to the user patient e.g., onboarding messaging and reminders/alerts.	So that patients are kept updated and understand when their Remote Monitoring officially starts.	Patients	Must	Alex Tealdi, Carly Ings, Liz Tate, Cheryl O'Sullivan

2.2 Step 2: Monitoring Requirements



Monitoring Requirements					
ID	Requirement	Rationale	Users	MoSCoW	Owner
Remote Monitoring setup					
2.2.1	There shall be two clearly distinct dashboards produced by the software. (1) Patient dashboard For the patient to use, enabling patients to do the following (examples, not an exhaustive list): • View their clinical information. • Provide their clinical information. • Provide answers to questionnaires. • Trend analysis of vital signs/symptoms in days/weeks and months for intuitive insight to triggers Patient dashboard (2) Professional dashboard For the professional to use, enabling professionals to do the following (examples, not an exhaustive list): • Monitor patients. • Manage Alerts. • Case manage. Professional dashboard	So that Patients can provide their information, to then be reviewed by an appropriate professional user.	Patients Professionals	Must	Crystal Dennis Alex Tealdi Carly Ings
Patient dashboard					

2.2.2	Patient use of software Patient dashboard The Software shall enable patients to view their clinical information in a place that is easy to use and intuitive to access. The software will be accessible to the patient in their own home.	So that the patient can use the software intuitively, without any issues in their own home.	Patient	Must	Crystal Dennis
2.2.2.1	One single dashboard for patients Patient dashboard Patients shall have one single dashboard (rather than multiple).	If the patient requires more than one module to be enabled, there is a single dashboard which serves all their needs under one login, keeping things simple for the patient.	Patient	Could	Crystal Dennis
2.2.3	Third party Access Patient dashboard There shall be the capability within the Patient dashboard for patients to allow third party users, such as their Next of Kin, carers (and those important to them) to support their remote monitoring.	Patient able to utilise remote monitoring service with support from their circle of care (supports individuals with access needs and physical or mental disabilities that require assistance in engaging with digital health technologies), and Dorset ICB supports a push to reduce health inequalities and widen access to Remote Monitoring / LTC management pathways.	Patient	Must	Crystal Dennis
2.2.4	Status updates Patient dashboard The patient shall be able to view their remote monitoring status via the Patient Dashboard (This shall include (but is not limited to) whether they are admitted/discharged/transferred, and which team or clinician they are under where applicable).	So that the patient is kept informed and understands when they are or are not being actively monitored by a clinician.	Patient	Should	Crystal Dennis
Professional user requirements – professional dashboard					

2.2.5	Professional dashboard Professional dashboard The software shall include a professional dashboard with clear, intuitive UX for ease of navigation and use.		Professionals	Must	Crystal Dennis, Liz Tate
2.2.6	One single dashboard for professionals Professional dashboard Professionals shall have one single dashboard (rather than multiple).	If the professional needs to monitor patients across multiple modules, this can be done through one dashboard.	Professionals	Could	Crystal Dennis
Workflow - Monitoring					
2.2.7	Patient input Patient dashboard Patients shall be able to provide their clinical information (Observations, Signs and Symptoms) via the Patient remote monitoring software. This shall include: - Clinical readings or observations - Answers to preset clinical and non-clinical questionnaires	So that patients can be monitored safely. The clinical readings can be used to detect early on when a patient begins to deteriorate. Qualitative questions can help build a better understanding of the patient's needs and provide context.	Patient	Must	Alex Tealdi, Carly Ings, Liz Tate
2.2.7.1	Prompts to complete. Patient dashboard The Patient Software shall utilise prompts which support users to complete select data fields (validation logic).	So that the software helps explain why an error has occurred and navigates them through the error.	Patient	Should	Alex Tealdi, Carly Ings
2.2.7.2	Smart Question Logic Patient dashboard <i>(Likely to be relevant when a patient is using multiple Remote Monitoring / Management modules)</i> The Patient software shall have user centered design and logic which determines from the modules the patient is on, how to present patients information and questions	So that the user experience and journey is seamless preventing the user from having to enter the same information more than once.	Patient	Should	Liz Tate, Cheryl O'Sullivan

	once (rather than repeating the same questions for different modules).				
2.2.8	Issue, record, review and store surveys Patient dashboard Professional dashboard The software shall securely surface all patient contributed data.	So that as well as collecting raw data, we can ask qualitative questions of patients which measure how well they are feeling - which helps to build a bigger picture of a person's health.	Clinicians	Must	Graham Sheppard, Paddy Baker Liz Tate
2.2.9	Raising Alerts Patient dashboard Professional dashboard The Software shall raise an appropriate alert if patient results are concerning (or other criteria are met, such as agreed frequency of results to be provided). The software shall use a risk rating system (e.g.: RAG rating system to define the severity / seriousness of these alerts - Red / Amber / Green).	So that the appropriate escalation can be taken for that patient	Patients Clinicians	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Karen Bowers
2.2.10	Case management Professional dashboard The Software shall enable clinicians to effectively case manage their patients via the professional RM Dashboard. <u>This shall include:</u> - The ability for individual professional users to have an overview of their caseload. - Clinical facing dashboards that operate at system, borough, PCN, practice and patient level - Ability to break down into admin / clinical tasks. - Filters on RAG results / Owner of patients by clinician or secondary care consultant or team (this should also be clearly visible on the page) /	So that the management of patients is intuitive and any way of filtering by results can be achieved - providing an excellent level of usability for the professional.	Clinicians	Must	Keith Gomes Pinto, Liz Tate, Karen Bowers

	PCN or practice. We also need to be able to customise the filters for cohorts of patients. - Filters on results may also include the ability for professionals to filter by: - Only their patients. - Patients with an alert (and by alert type). - Age of alert (how long ago first raised). - Admin – ability to define these – registration, inactivity, response awaited, etc Clinical – ability to define these – alert RAG, management issue, etc				
2.2.10.1	Task management Professional dashboard Professional users shall have task management capability, which includes: - The Dashboard generating relevant tasks for professional users to complete, providing a more engaging and direct user experience, with the ability for professionals to respond to tasks (such as alerts) and manage these as a part of case management. - The ability to create / assign (and reassign) / update / delete / complete tasks. - The ability for professionals to task each other as well.	So that patients are safely and effectively managed, utilising tasks as a way of tracking actions and for auditing purposes.	Clinicians Professionals	Must	Keith Gomes Pinto, Liz Tate, Karen Bowers
2.2.10.2	Task work listing Professional dashboard Professional users shall be able to see in the professional Dashboard an active worklist of tasks	So that this enables clinicians to tackle the patients with higher levels acuity, with any actions that are taken being captured in response to the task.	Clinicians Professionals	Must	Keith Gomes Pinto, Duncan Pike, Liz Tate, Karen Bowers

	requiring review, which have been automatically prioritised based on urgency of response required. The ability shall be provided for professional users to view tasks that have been actioned by other professionals.				
2.2.10.3	Notifying professionals Professional dashboard the software shall have the functionality to notify professional users e.g. task allocation and these should be customisable e.g. "new patient allocated to remote monitoring module for review"	So that important notifications are prioritised within the tool, managing logic on the professional user's behalf	Clinicians	Should	Alex Tealdi, Liz Tate
2.2.11					
2.2.12					
2.2.13	Customise parameters/thresholds Professional dashboard Clinical users will be able to be able to customise the parameters of patient workflows and set clinical thresholds in the Professional Dashboard recognising the patient's baseline observations, signs and symptoms. We would expect this to be achieved by the software allowing specifically nominated super-users and clinical groups to be able to personalise clinical thresholds.	So that we are able to make ensure our pathways are developed based on our patient's bespoke clinical needs.	Clinicians	Must	Keith Gomes Pinto, Liz Tate, Karen Bowers
2.2.14	Comment functionality Professional dashboard The software shall enable any professional users to leave comments for each other to enable safe monitoring and management of the patient (visible only to other professional users on the software). Ideally, this should be achieved through a separate tab for comments.	So that clinicians have the ability to communicate with each other enabling secure and safe monitoring and management of the patient. Has the ability to provide updates in patient's care saving time.	Clinicians Professionals	Must	Keith Gomes Pinto, Liz Tate, Cheryl O'Sullivan

2.2.15																	
2.2.16	Logic and decision support Professional dashboard The software shall support professional users in building bespoke rules and logic that underly the alert functionality in prompting clinicians to action them.	So that there is clarity in the clinician’s understanding about when to act and when to escalate appropriately standardising practice as best as possible.	Clinicians	Should	Keith Gomes Pinto, Liz Tate, Karen Bowers												
2.2.17	EPR Dashboards The software shall integrate clinician-facing dashboards directly into the EPR used by the clinical professional, using individual patient context (NHS number), where the clinical system allows this (e.g., use of dynamic URLs containing the patient’s NHS number from SystmOne). <i>The following are the names of these EPR’s, and their priority:</i> <table><tr><th>Trust Name</th><th>System (EPR) name</th><th>Individual MoSCoW Priority</th></tr><tr><td>Primary / Community Care</td><td>TPP SystmOne</td><td>MUST</td></tr><tr><td>University Hospital Dorset</td><td>Graphnet</td><td>Could</td></tr><tr><td>Dorset County Hospital</td><td>Fortrus EPR</td><td>Could</td></tr></table>	Trust Name	System (EPR) name	Individual MoSCoW Priority	Primary / Community Care	TPP SystmOne	MUST	University Hospital Dorset	Graphnet	Could	Dorset County Hospital	Fortrus EPR	Could	So that the EPR used by the clinical users can be used to find relevant dashboards for their patients.	Clinicians	Must	Keith Gomes Pinto, Liz Tate
Trust Name	System (EPR) name	Individual MoSCoW Priority															
Primary / Community Care	TPP SystmOne	MUST															
University Hospital Dorset	Graphnet	Could															
Dorset County Hospital	Fortrus EPR	Could															
2.2.17.1	Auditing data Professional dashboard The professional Dashboard shall display input dates times relating to information completed / updated and details of the clinicians who documented the information.	So that the overall picture of updates to the software is auditable and traceable of what happened when.	Clinicians	Must	Liz Tate, Karen Bowers												
2.2.18	Single Sign on Professional dashboard	So that the software is use-able for professional users without	Clinicians Professionals	Should	Graham Sheppard, Duncan Pike												

	Professional users shall be able to launch the software without the need for a separate login to the local system, when searching for an individual patient, ideally using smartcards to access where possible. There should also be no need for a separate login when searching for other patients once the system has launched.	needing multiple (unnecessary) button clicks			
2.2.19	Access Reviews Professional dashboard In organisations where professional users cannot access the software via their usual EPR or the HIE, the software shall provide the ability for professional users to be automatically prompted and provided with the automated ability to verify and update their user profile to ensure their right to access patient information is periodically verified.	So that We are proactive in ensuring only the appropriate users have access to patient data.	Clinicians Professionals	Could	Graham Sheppard, Paddy Baker
2.2.20	Managing change in clinician Professional dashboard If and when there is a change in who the responsible clinician is for the patient, and both clinicians use the software, this software shall enable the professional user to assign the patient to another clinician who will be responsible for that patient's care (For example, to a clinician in an Acute Ward). The new responsible clinician will need to accept this transfer of care via the software before the handover is complete.	So that there is clear ownership and accountability for that patient's care with any issues or concerns being escalated and addressed in a timely and safe manner.	Clinicians	Should	Liz Tate, Crystal Dennis, Keith Gomes Pinto
2.2.21	Professionals User experience Professional dashboard There shall be one single dashboard for professional remote monitoring (as opposed to separate).	So that clinicians and remote monitoring staff can access the relevant data for their patients through one dashboard and one login.	Clinicians Professionals	Could	Crystal Dennis
Remote Monitoring ONLY Specific Capability					

2.2.22	Continuous Monitoring Patient dashboard Professional dashboard The Software shall enable continuously (or almost continuously) monitoring patients through real-time data feeds, including receiving and updating data for patients.	So that any data for a patient which falls outside of our acceptable thresholds (highlights clinical concern) can be feasibly acted on with immediacy.	Patient	Should	Keith Gomes Pinto, Crystal Dennis Liz Tate Cheryl O'Sullivan
2.2.23	Passive Monitoring Patient dashboard Professional dashboard The Remote Monitoring software shall enable monitoring of the patient without the patient's active involvement.	So that we have software whereby patients can use (for example) wearable devices that feed information into the software automatically and do not need to actively put their readings in to the software in order for this to work	Patient	Could	Keith Gomes Pinto, Crystal Dennis Liz Tate Cheryl O'Sullivan
2.2.24	NEWS2 Professional dashboard The Software shall utilise News2 - the national early warning system, indicating early signs of an individual becoming unwell. The Software shall have the ability to collect clinical data and observations, to then produce NEWS2 scores that highlight when patient users are presenting early warning signs.	So that we use the correct national standard for early warnings of deterioration	Clinicians	Must	Keith Gomes Pinto Liz Tate Cheryl O'Sullivan
Patient and Professional shared monitoring functionality					
2.2.25	Identity Authentication Patient dashboard Professional dashboard The Software shall authenticate the identity of users.	So that only appropriate users can access the Software	Patients Clinicians Professionals	Must	Graham Sheppard, Paddy Baker

2.2.26	2nd Factor Authentication. Patient dashboard Professional dashboard The software shall authenticate any / all users using 2nd Factor Authentication upon login.	So that We can be confident that only appropriate users are accessing patient data	Patients Clinicians Professionals	Must	Graham Sheppard
2.2.27	Storing information Patient dashboard Professional dashboard The Software shall securely record and store a person's vital signs/observation scores, including (but not limited to): - NEWS2 - Pulse rate - Respiratory rate - Oxygen saturation - Temperature - Mobility - Weight - Blood pressure - Ability to monitor any other pathway-specific clinical measurements* <i>*To be agreed as part of pathway co-design.</i>	So that we keep a record of results for our patients, which can then be analysed to establish whether further actions / escalation is needed.	Patient Clinicians Professionals	Must	Keith Gomes Pinto, Crystal Dennis Liz Tate Cheryl O'Sullivan
2.2.28	Set parameters. Patient dashboard Professional dashboard The software shall enable the setting of parameters of the frequency of clinical readings provided by the patient.	So that there is logic which the software can use to prompt patients if they don't provide readings, and alert us if a patient is not providing these readings	Clinicians	Must	Crystal Dennis, Liz Tate Cheryl O'Sullivan Keith Gomes-Pinto

	Clinical users need to then be able to select within their dashboard (and update at any time) these clear parameters that define how often (and on which days) patients (at either a collective or individual level) must provide their readings on their dashboard.				
2.2.29	Acceptability rules Patient dashboard Professional dashboard There shall be parameters within the software which define acceptable / unacceptable results for a patient, as well as at what intervals results must be provided. See the next section (Alert Management) for what should happen if these thresholds are exceeded.	So that we can respond effectively if a patients results are outside of the acceptable range, or they fail to provide results altogether.	Patients Clinicians	Must	Keith Gomes Pinto, Crystal Dennis, Karen Bowers Liz Tate Cheryl O'Sullivan
2.2.30	Unified and coherent display Patient dashboard Professional dashboard The software shall be able to present information from multiple sources (including medical devices, patient-submitted data and EPR/HIE) in a unified and coherent manner for end users.	So that regardless of how the information is input, the output for end users is consistent and can be easily read and understood.	Patients Clinicians Professionals	Should	Alex Tealdi, Carly Ings, Liz Tate Cheryl O'Sullivan Keith Gomes-Pinto Karen Bowers

2.3 Step 3: Alert Management Requirements

Long Term Condition Remote Management Alert Management process



Long Term Condition Remote Management Specific Requirements					
ID	Requirement	Rationale	Users	MoSCoW	Owner
2.3.1	Patient Signpost and Safety Netting Patient dashboard If data submitted is outside the pre-defined thresholds, patients will be appropriately signposted to the right resources and safety netted within the patient-facing dashboard. Depending on how the clinical pathway and management is defined, the patients may need: • Signposting • Safety netting advice • Direct advice (Call 111/999/OOH/responsible team) • To be prompted to resubmit data within a certain timeframe.	So that patient is empowered to self-care and understands when to seek help.	Patients	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Cheryl O'Sullivan
2.3.1.1	Adaptable Signposting Content and Resource Patient dashboard Professional dashboard The signposting & overall content that a patient is directed to through the patient-facing dashboard should be customisable / locally configured by NHS Dorset.	So that patient can be supported by local resources and services where applicable	Clinicians System Administrators	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Karen Bowers, Cheryl O'Sullivan

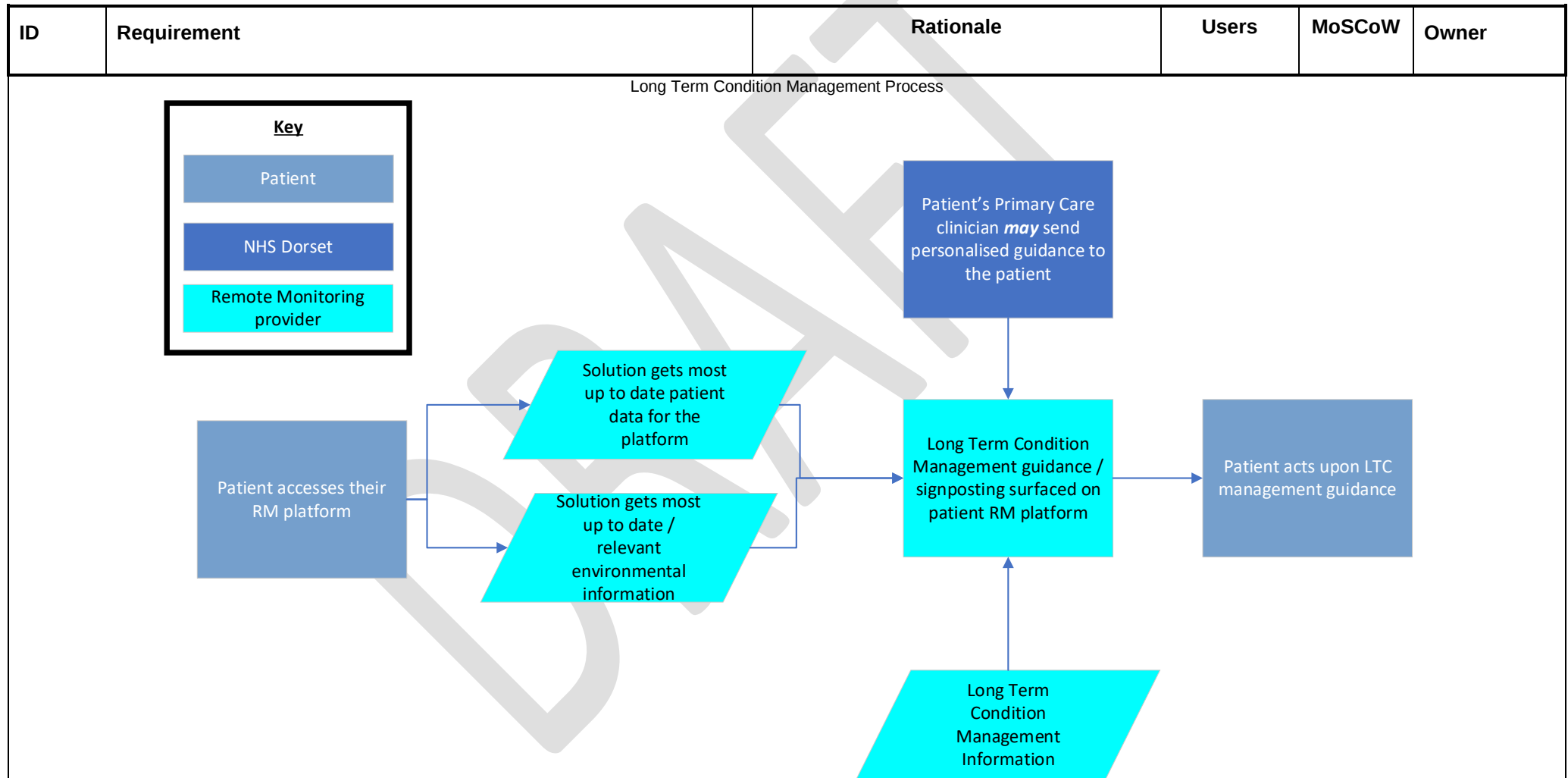
2.3.2	Notify/alert professionals of outstanding actions Professional dashboard The Professional RM Dashboard shall alert clinical users that action is required as defined by the clinical escalation pathway and thresholds set.	So that the clinician can be confident that the software will highlight when a patient needs their attention or input, ensuring they are tended to promptly and safely.	Clinicians Professionals	Must	Keith Gomes Pinto, Liz Tate
2.3.3	Prioritising Alerts. Professional dashboard Professional users should be able to filter alerts within their dashboard, based on level of risk (RAG rating) and timeline (older alerts can be prioritised)	So that the clinician can prioritise alerts based on level of urgency and delay in response.	Clinicians Professionals	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Karen Bowers
2.3.4	Bespoke professional-to-patient Alerts Patient dashboard Professional dashboard Clinical users shall be able to use the professional RM Software to create bespoke or utilise pre-templated manual alerts / notification / advice that can be surfaced to the patient through the patient dashboard.	So that if there is something specific to their condition that clinician would like to highlight to patient, they can use the software to communicate this (rather than relying only on email / phone calls).	Clinicians	Should	Keith Gomes Pinto, Liz Tate, Cheryl O'Sullivan
2.3.5	Inactive user identification Professional dashboard The professional Dashboard shall enable any professional or system administrator to identify which patients are not using the remote monitoring technology.	So that these patients can be contacted, and supported or offboarded from the technology depending on what is most appropriate for the patient.	-Clinicians -Professionals -System Administrators	Must	Keith Gomes Pinto, Liz Tate, Cheryl O'Sullivan
2.3.6					
Patient Remote Monitoring Dashboard – Receiving Alerts					
2.3.7	Signpost patient from alert Patient dashboard The Patient dashboard shall signpost the patient appropriately when an alert is raised. When a RED alert is raised (for example), the patient needs to be signposted appropriately	So that patient is able to respond appropriately.	Patients	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate Cheryl O'Sullivan

	using push notifications and software-based messaging, based on the precise and bespoke nature of the alert, to advise them of next steps. The patient shall be advised appropriately via this signposting what they need to do next (for example: Call 999 / Contact their responsible clinician).				
2.3.7.1	Signpost Content Patient dashboard Professional dashboard The signposting & overall content that is shown to a patient on their dashboard upon an alert being raised shall be customisable by us (Dorset ICS) depending on other measurable variants such as (but not limited to): - Time Alert was Raised - Whether the Remote Monitoring Team are within opening hours	So that patient given the right guidance in real time as to how they should respond to an alert.	Clinicians System Administrators	Should	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Karen Bowers Cheryl O'Sullivan
Professional Remote Monitoring dashboard – Receiving and creating Alerts					
2.3.8	Notify professionals of actions Professional dashboard The Professional dashboard shall notify professional users that action is required, including notifying them that alerts have been raised, and why (<i>eg: clinical thresholds have been surpassed</i>). This shall also include the ability to notify users that critical actions have taken place.	So that the experience is engaging and uses prompts (notifications) to engage users rather than relying on the user solely to extract from the software what is or isn't important.	Clinicians Professionals	Must	Keith Gomes Pinto, Liz Tate Cheryl O'Sullivan Karen Bowers
2.3.9	Show Professional what patient was shown. Professional dashboard The signposting / content that has been shown to a patient prompted by an alert also needs to be captured (to be then surfaced within the professional's dashboard).	The clinician needs to be able to see what the patient has been signposted to do in the event that an alert has been raised.	Clinicians Professionals	Must	Keith Gomes Pinto, Liz Tate Cheryl O'Sullivan Karen Bowers

2.3.10	EPR alert integration. Professional dashboard (In the event that a red / concerning alert is raised) an alert shall be generated in the EPR system the responsible clinician of the patient uses, which notifies them that the patient has a <table><tr><th>Trust Name</th><th>System (EPR) name</th><th>Individual MoSCoW Priority</th></tr><tr><td>Primary / Community Care</td><td>TPP SystmOne</td><td>Must</td></tr><tr><td>University Hospital Dorset</td><td>Graphnet</td><td>Could</td></tr><tr><td>Dorset County Hospital</td><td>Fortrus EPR</td><td>Could</td></tr></table> concerning result.	Trust Name	System (EPR) name	Individual MoSCoW Priority	Primary / Community Care	TPP SystmOne	Must	University Hospital Dorset	Graphnet	Could	Dorset County Hospital	Fortrus EPR	Could	So that this information is immediately accessible to clinician, without needing to consult a separate	Clinicians Professionals	Must	Graham Sheppard, Duncan Pike, Karen Bowers
Trust Name	System (EPR) name	Individual MoSCoW Priority															
Primary / Community Care	TPP SystmOne	Must															
University Hospital Dorset	Graphnet	Could															
Dorset County Hospital	Fortrus EPR	Could															
2.3.11	Prioritising Alerts. Professional dashboard Alerts shall be able to be prioritised through the professional dashboard if they have been raised for longer, without the patient either having been contacted or having contacted us successfully.	So that higher risk alerts can be handled first	Clinicians Professionals	Must	Keith Gomes Pinto, Alex Tealdi, Liz Tate, Karen Bowers												
2.3.12	Track patient outcomes Professional dashboard The Professional dashboard shall track outcomes of the patient after an alert has been raised. This functionality shall include getting information from relevant EPR systems where patient contact may have been recorded, to provide a holistic view to clinicians on the professional remote monitoring software of what has happened to the patient since the alert was raised.	So that if the patient requires further escalation, the software captures this for us. Tells us if patient has acted upon their escalation instructions	Clinicians Professionals	Should	Keith Gomes Pinto, Graham Sheppard, Liz Tate												
2.3.13	Bespoke professional-to-patient Alerts	So that if there is something specific to their condition that clinician would	Clinicians	Should	Keith Gomes Pinto, Liz Tate,												

	Patient dashboard Professional dashboard Professional users shall be able to use the professional dashboard to create bespoke or utilise pre-templated manual alerts / notification / advice that can be surfaced to the patient through the patient dashboard.	like to highlight to patient, they can use the software to communicate this (rather than relying only on email / phone calls).			Cheryl O'Sullivan
Professional Remote Monitoring dashboard – Closing Down Alerts					
2.3.14	Close down alerts. Professional dashboard Clinical professional users shall be able to close a patient alert down on the professional dashboard.	So that If a patient's issue has been resolved (or is in hand elsewhere) clinicians do not need to chase this up further, and so the alert needs to be closed.	Clinicians	Must	Liz Tate, Karen Bowers
2.3.15	Rationale to close down alert. Professional dashboard The Professional dashboard shall enable clinical users to select certain conditions to be met e.g. a rationale (from a list of options that NHS Dorset approve) when an alert is closed. This rationale shall be recorded.	So that we can track the reasons that an alert has been closed, and track if the rationale for closing is inappropriate.	Clinicians	Must	Alex Tealdi, Liz Tate, Karen Bowers
2.3.16	Insufficient rationale logic. Professional dashboard The Professional dashboard shall have logic that if an alert is closed without sufficient rationale (logic for which needs to be inbuilt into the software and co-designed with NHS Dorset), this is escalated (for example, through another alert to clinician).	So that we can check any closing of alerts that may be inappropriate or closed in error.	Clinicians	Should	Alex Tealdi, Liz Tate, Karen Bowers

2.4 Step 4: LTC Management Requirements



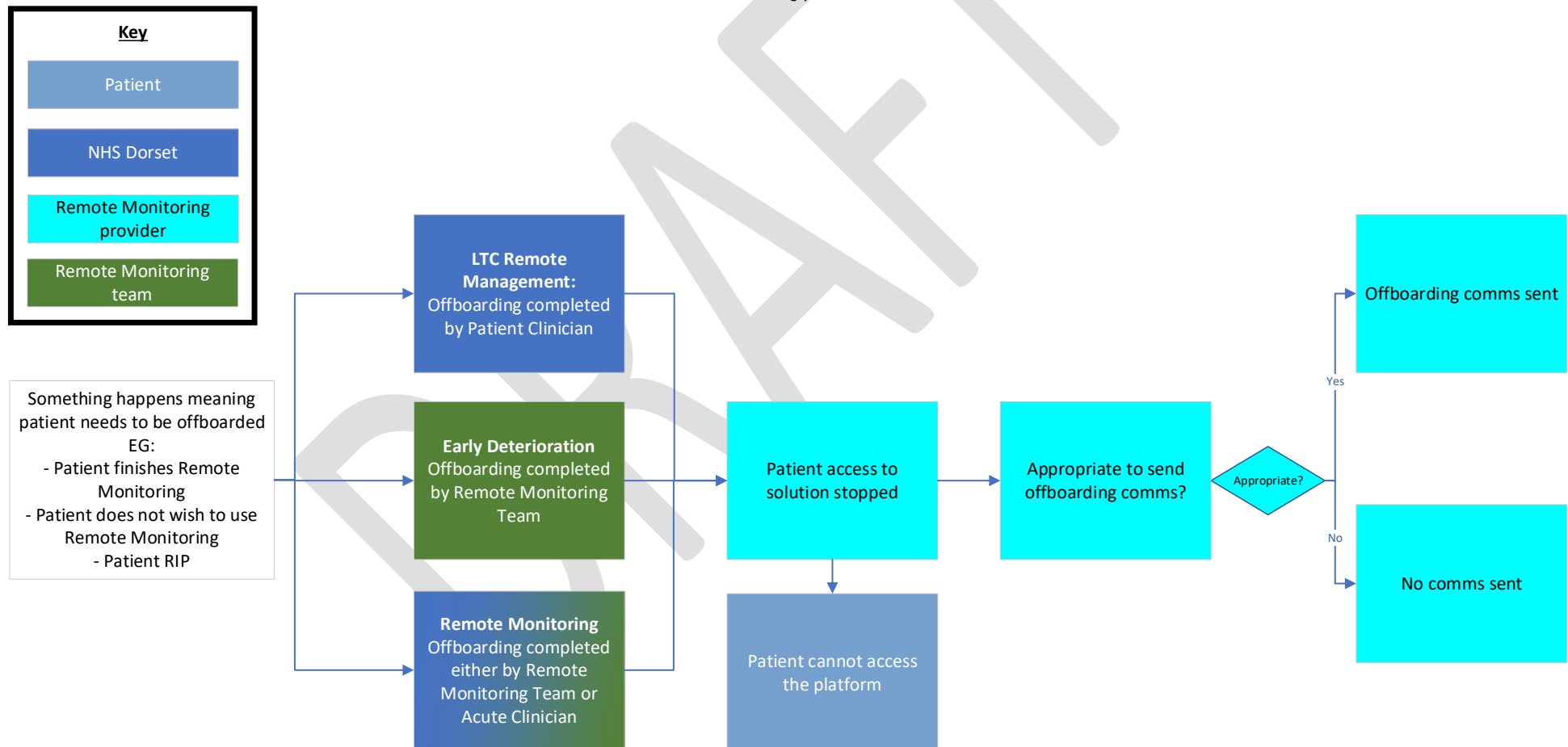
2.4.1	Self-management Resources There shall be self-management resources made be available to patients, via their dashboard, aligned to NICE guidance and best practice that will help them to manage their long-term condition. There shall be a variety of these self-help resources which are specific and tailored to their specific condition(s).	So that I am able to manage my condition myself, using advice and guidance available to me 24/7 without necessitating an appointment with my GP.	Patients	Must	Carly Ings, Cheryl O'Sullivan
2.4.2	Services scope for LTCRM The following services shall be in scope for Long Term Condition Remote Management: • Asthma • Heart Conditions (heart failure) • COPD • Diabetes		Patients	Must	Carly Ings, Cheryl O'Sullivan
2.4.3	Interactive Guidance Interactive self-management guidance shall be provided to patients via the patient dashboard, that reacts to information that the patient and the environment around them provides. For example: If a patient has asthma, they need to be told about their local air quality and weather.	So that the information given is tailored to me and my environment for the condition. This makes the information both practical and use-able.	Patients	Must	Carly Ings, Cheryl O'Sullivan
2.4.4	Mandatory questions The Patient software design shall enable NHS Dorset to choose to present monitoring questions to the patient that must be answered (mandatory) before they can access self-help guidance.	So that patients continue to provide their readings, which we can then act upon if these are concerning and require escalation / follow up	System Administrators Clinicians	Should	Keith Gomes Pinto, Liz Tate, Karen Bowers Cheryl O'Sullivan

2.5 Step 5: Offboarding Requirements



Offboarding requirements

Offboarding process



ID	Requirement	Rationale	Users	MoSCoW	Owner
2.5.1	Ending Remote Monitoring. The professionals dashboard shall provide the capability for clinical professional users to end the Remote Monitoring for any patient user.	So that patients can be offboarded in any situation where the software is no longer relevant to them. For example, if they are no longer on the clinical pathway which requires Remote Monitoring, or the patient does not wish to use the software any further.	Clinicians Patients	Must	Keith Gomes Pinto, Liz Tate, Karen Bowers, Cheryl O'Sullivan
2.5.2	Send Offboarding Comms. When a patient is off boarded by a professional, the professional shall be able to choose via their dashboard whether they send offboarding communications to the patient (and by which methods). If the patient is recorded to have died, then there shall be functionality which defaults to no comms being sent.	So that patients are kept informed when they are being removed from the software, and only in circumstances that are appropriate.	Clinicians Professionals Patients	Must	Keith Gomes Pinto, Crystal Dennis
2.5.3	Status to Primary Care Record. When a patient is offboarded, an update of this status shall be shared with the patients GP (Primary Care) Record. This is, currently, recorded on TPP SystemOne.	So that the patients Primary Care GP is aware of their Remote Monitoring Status	Clinicians Professionals	Must	Keith Gomes Pinto, Crystal Dennis, Cheryl O'Sullivan
2.5.4	Rationale to offboard. When a patient is offboarded from the software, by a professional user using the software, a rationale needs to be provided by the professional user from a list of drop downs (which are agreed by NHS Dorset).	So that it is clearly understood and recorded why the patient is no longer on the software.	Clinicians Professionals	Must	Keith Gomes Pinto, Karen Bowers
2.5.5	Patient RIP recording. The software shall have the capability when offboarding to record when a patient has died. This record should then prevent the patient from being re-added to the software unless this record is updated (if this was recorded in error).	So that patients cannot be sent any comms about Remote Monitoring in the event they have sadly passed away.	Clinicians Professionals	Must	Paddy Baker, Liz Tate, Karen Bowers

2.6 General Functional Requirements



ID	Requirement	Rationale	Users	MoSCoW	Owner
Patient and Professional Communication					
2.6.1	Professional co-working The software shall support professional users to communicate with each other. This could be either via the software directly, or via existing or emerging messaging or notification channels.	So that we enable a collaborative approach for remote monitoring	Clinicians Professionals	Should	Keith Gomes Pinto, Liz Tate, Cheryl O'Sullivan
2.6.2	2-way messaging The software shall provide the ability for professional users to speak to patients via the software, utilising 2-way messaging. This messaging functionality must be able to be turned on or off on a patient-by-patient basis by professional users. The software shall record when messages are delivered / seen.	So that clinicians can engage with patients regarding their remote Monitoring, and are also able to restrict this functionality only to when they are actively using this so that patients do not simply send through messages which are not being monitored (which raises potentially very serious clinical safety issues).	Patients Clinicians Professionals	Should	Keith Gomes Pinto, Liz Tate, Karen Bowers, Cheryl O'Sullivan
2.6.3	Integrate new tech. The software will be able to integrate with new device capabilities (eg: Bluetooth enabled devices) as this type of technology becomes available and / or standard.	So that we meet the evolving technological needs of the Remote Monitoring service	Patient	Should	Crystal Dennis
2.6.4	Clinical Communication modes The software shall allow users to access the different modes of clinical communication including video consultations with multiple participants, messaging via text/email, image sharing and advice and guidance support.	So that Communication is a fully supported capability within the software, enabling professional and patient to communicate with one another effectively.	Patients Clinicians Professionals	Must	Crystal Dennis
2.6.5	Patient to professional no-result rationale The software shall have the ability for patients to send a message specifically to let professional users know that they don't want to submit observation or reduce number of these.	So that patients can engage with the process, and advise in advance if they are not providing readings (which also assured clinical staff that	Patients Clinicians	Should	Keith Gomes Pinto

	This should be achieved through multi-choice options, rather than free text (to reduce clinical risk). Professional users should then be shown this information through their dashboard.	there is no urgent reason underpinning this).			
Data Analysis					
2.6.6	Analyse and Audit data System administrators shall be able to analyse, and audit select data from the software. The data which NHS Dorset needs to be able to analyse to be fully decided upon and agreed by NHS Dorset. This shall include (but is not limited to) an analysis of how / if patients are utilising the software.	So that we can meet our analysis and audit targets.	System Administrators	Must	Crystal Dennis, Alex Tealdi, Carly Ings
2.6.7	Capture pathway data The software shall capture full end-to-end pathway data: For example, referral, consent, triage, etc.	So that we can capture and then analyse the whole user journey.	System Administrators	Must	Crystal Dennis, Alex Tealdi, Carly Ings
2.6.8	Audit of changes The software shall enable system administrators to audit the history of changes to remote monitoring activity (for example, who contributed/edited specific data points, and the relevant date stamps for each change to the monitoring data).	So that we get a rich picture of a patients entire journey. This may be especially critical should we need to understand in the future what we as a health service did or did not know about a patient at any given point in time.	System Administrators	Must	Keith Gomes Pinto, Liz Tate
2.6.9	Data Extract Tool The software shall provide a data extract tool, to enable offline analytical capabilities, and to integrate with local population health data tools, Including the Oxford Pseudonymisation tool. To this end, the software shall have integration with DiiS / able to inward feed data into DiiS	So that we can analyse the data locally, extracting the data as appropriate for us (Dorset ICS)	System Administrators	Must	Graham Sheppard, Crystal Dennis
2.6.10	Ready-To-Use audit functionality The software shall contain some audit functionality which is ready built by the software provider, which ready for NHS Dorset to use. This shall include (but is not limited to): • Ability to produce standard statistics regarding remote monitoring software, remote monitoring usage data, total	So that we have a quality and rich analytical capability, meeting our own requirements as an organisation of the items we would like to be able to audit for degree of success.	System Administrators Clinicians	Should	Graham Sheppard, Crystal Dennis

	amount of information added and current plan status. • Software has auditing capability to generate reports of which users accessed, edited, and viewed data within the Software. • Software generates standard user statistics. • Ability to download the standard statistics as CSV, Excel files, PDFs and other formats. • Ability for users to create ad-hoc reports based on business questions they would like answered. • Ability to customise report writing, enabling report writing on any data field and providing wizard to guide report creation and formatting. The ability for users to save an unlimited number of customised reports. • Software provides a clear data dictionary that articulates the purpose of the report, definitions of the data fields and documents how the data has been transformed. • Ability to capture user and clinician satisfaction within the system and provide regular feedback reports. • Clinical safety and outcomes reports are available through the reporting Software. • Ability to measure the number of patients using the software that result in treatment escalation or change. • Ability to provide service usage reporting anonymised data at an ICS level to update, optimise operational and strategic decision-making in line with the ICO Anonymisation Code of Practice.				
2.6.11	Access to reports The Software shall provide the capability for professional users to access reports (the design of which shall be in collaboration with Dorset ICS), either directly via their RM dashboard or via a connected solution.	So that professional users have ready access to intelligence regarding the software.	Clinicians Professionals	Should	Keith Gomes Pinto, Crystal Dennis
Integrations					
2.6.12	Acute EPR integration There shall be Integration between the software and our existing EPR solutions across Acute care. These (at present) are:	So that the information captured in the software is made readily available to clinicians who are likely to help the patient	Clinicians System Administrators	Should	Graham Sheppard, Duncan Pike

	- EMIS Camis (University Hospitals Dorset) - Fortrus EPR (Dorset County Hospital)				
2.6.13	Primary and Community EPR Integration There shall be integration between the software and our existing EPR solutions in Community Care (at present this is TPP SystmOne) This shall include the ability SNOMED codes to be pushed into SystmOne.	So that the results from monitoring can be surfaced for the patient's primary care clinician.	Clinicians System Administrators	Must	Graham Sheppard, Duncan Pike
2.6.14	Dorset Care Record Integration The software shall have the capability for select clinical information from the software (selected and to be specified by Dorset ICS) to flow into the Dorset Care Record data service as flat file FHIR resources to support direct care and the production of a consistent data layer.	So that shared care records for patients are substantial, rich in information and useful for clinicians and patients alike.	Clinicians System Administrators	Should	Graham Sheppard
2.6.15	Patient to healthcare provider sharing The software shall provide the capability for patients to share software-initiated documents with multiple healthcare providers, including their GP.	So that we improve and accelerate treatments across care settings with greater confidence.	Patients Clinicians	Should	Keith Gomes Pinto, Cheryl O'Sullivan
2.6.16	Share information between Healthcare Providers The software shall have the capability for professionals to share sensitive information between different health providers when there is a valid lawful basis for processing personal data (including public interest, public health, to provide direct care).	So that the care of the patient can be fully enabled across multiple healthcare organisations and professions.	Clinicians Professionals	Could	Crystal Dennis, Paddy Baker
2.6.17	NHS App Integration The software shall integrate with the NHS App and display remote monitoring outputs according to the NHS App design style. Integration with the NHS App includes (but is not limited to) notification and messaging functionality. The NHS App should become the normal end point for data.	So that patients who use the NHS app can have a single point of access for their information summarised.	Clinicians System Administrators	Should	Crystal Dennis
Other Functionality					
2.6.18	Print RM Outputs The software shall provide the capability for professional users to print remote monitoring outputs	So that this supports the transfer of care and offline review.	Clinicians Professionals	Should	Liz Tate, Cheryl O'Sullivan
2.6.19	Device Agnostic The software shall be either be device-agnostic or able to integrate with CE-marked prescribed medical devices	So that multiple device types can be used for the patient monitoring, which	System Administrators	Must	Keith Gomes Pinto, Graham Sheppard, Duncan Pike

	required by local pathways, including integrated communication to avoid transcription errors.	ultimately makes the software more accessible to patients.			
2.6.20	Reporting issues and incidents The software should provide an automated mechanism for users to report issues, incidents, and risks to the software provider.	So that the software provider can receive these and then implement improvements.	System Administrators	Must	Crystal Dennis
2.6.21	Continuous Improvement Clinical pathways shall be investigated by the software provider, and continuously improved based on feedback from users.	So that pathways are continuously improved whenever possible.	Clinicians System Administrators	Should	Graham Sheppard, Crystal Dennis
2.6.22	Customise Workflows capability NHS Dorset system administrators shall be able to customise the design of patient workflows, meaning they adhere to the NHS Dorset desired design. <i>We would expect this to be achieved by the software building the technological functions around the clinical pathways, with nominated super-users and clinical groups being able to modify the remote monitoring software based on clinical or system priorities. This includes but is not limited to the ability to modify functionality around data display, alerting, clinical thresholds, reporting and communication.</i>	So that we are able to make our pathways bespoke based on our pathway design requirements (as well as ensuring that we capture the information we need).	Clinicians System Administrators	Must	Crystal Dennis, Alex Tealdi, Carly Ings
2.6.23	Capability to implement Software. The software shall provide NHS Dorset with the ability to implement the software across an unlimited number of pathways.	So that we are able to re-use the software across the whole system where it is possible and appropriate to do so. This reduces the need for future Provider development cost, minimising the number of remote monitoring software required by the system and supporting a whole-system approach.	Clinicians System Administrators	Should	Graham Sheppard, Crystal Dennis
2.6.24	Annual Reviews The software shall have the ability for both: - A clinician to perform an annual review of patient's condition within their professional dashboard.	So that the information in the software can be used to support an enriched and full review of a patient's condition, based on their health observed in the dashboard.	Clinicians Patients	Must	Cheryl O'Sullivan Crystal Dennis Carly Ings

	- A patient to complete their own in-dashboard self-review of their condition. These annual reviews must be then able to be pushed / effectively stored within the patients Primary Care Record (currently this would need to be in TPP SystmOne). The start of this process (prior to the assessment itself) may be achieved (for example only) by integration with TPP SystmOne to find patients with annual reviews due. Patients can then be automatically contacted for their annual review.				
2.6.25	Devices to be provided. Devices shall be provided by the provider, to the user-patient, which can then be used to capture their clinical readings e.g. vital sign medical devices.	So that patients do not rely on their own equipment, which may not be fit for purpose	Patient	Could	Crystal Dennis, Alex Tealdi, Carly Ings
2.6.26	Using personal devices Patients shall have the ability to use the dashboard to its full potential capability, regardless of whether they use their own smart devices.	So that the patient can feasibly use devices and products they are already familiar with, rather than needing to re-learn new technology.	Patient	Could	Crystal Dennis, Duncan Pike
2.6.27	Configure access. Professional dashboard the software will allow professional users and super users or administrators to configure roles	for a good professional UX and auditable actions.	-System Administrators -Clinicians -Professionals	Should	Graham Sheppard
2.6.28	Adding information to software Professional dashboard The software shall enable clinical and non-clinical professional users to view and/or add information to the remote monitoring software. Their ability to view and add information shall be based on their job roles and national role-based access standards.	So that, based on role-based access, only authorised users are able to edit information within the software.	Clinicians Professionals	Should	Crystal Dennis
2.6.29					
2.6.30					

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3 Non-functional Requirements

3.1 Security Requirements

NFR Rationale		
The software must be designed to protect sensitive patient information from: a) Unauthorised access b) Disclosure. And ensure that patient information is collected used, securely stored and shared in accordance with relevant privacy laws and policies. Requirements listed below:		
NFR Group Owners		
• Paddy Baker • Duncan Pike • Graham Sheppard		
Req. Ref	Requirement	Priority (MoSCoW)
3.1.1	<u>Confidentiality</u> The software must ensure: a) Security and confidentiality of personal data b) Protection against unauthorised access to data c) Protection against unauthorised disclosure of data d) Protection against unauthorised destruction of data	Must
3.1.2	<u>Integrity</u> The software must ensure that during storage, transmission, or processing data is not: a) Modified b) Corrupted c) Lost	Must
3.1.3	<u>Access controls and restrictions</u> The software shall enable control by system administrators, of access to the software and functions based on role-based access control (or claims-based access control).	Must
3.1.4	<u>Access control logic</u> The software must support role-based access control as per user types described on page 9	Should
3.1.5	The software must support Role Based Access Control in line with NHS Digital's national database of roles and permissions for healthcare workers (the RBAC database) National role-based access control (RBAC) for developers - NHS Digital	Must
3.1.6	<u>Availability to data and services</u> The software must ensure that authorised users have access to data and services when needed. Remote management and remote monitoring require 24/7 availability for the purpose of patient usage, with remote monitoring requiring the hours of 08:00 to 20:00, Mon-Sun for staff usage.	Must
3.1.7	<u>Accessibility</u>	Must

	The software must require users to log onto the solution by entering user ID and password, and once only regardless of how many different application modules are used subject to the level of access their job description dictates.	
3.1.8	<u>Authentication</u> All privileged accounts must have Multi-Factor Authentication (MFA) as per NHS https://digital.nhs.uk/cyber-and-data-security/guidance-and-assurance/multi-factor-authentication-mfa-policy DTAC C3.4	Must
3.1.9	The software must ensure that users are who they claim to be by verifying their identity E.g., via use of the NHS login and NHS identity programme. The system must use NHS Login if it uses an NHS number to identify a patient record. If the solution stores passwords itself it must do so using non-reversible encryption and the current good practice guidance on passwords issued by the National Cyber Security Centre NHS login for partners and developers - NHS Digital	Should
3.1.10	The software should be compatible with modern authentication sources such as Azure Active Directory, OAuth or SAML. Where practicable the solution should use the NHS login and NHS identity programme. The system must use NHS Login if it uses an NHS number to identify a patient record NHS login for partners and developers - NHS Digital	Should
3.1.11	<u>Biometric Authentication</u> The software could have the ability to authenticate patients biometrically.	Could
3.1.12	<u>Authentication without email</u> The software should be able to confirm identity of users without depending on the user's email address.	Should
3.1.13	<u>Patient Single Sign on through NHS login</u> Patients should only have to login through a single method, ideally through integration with NHS Login, either directly or through a third-party intermediary, to allow patients to provide NHS Login verified digital proof of identity to access their account and health record.	Should
3.1.14	<u>Authorisation</u> The software must ensure that users are only granted access to resources and functions that they are authorised to use.	Must
3.1.15	<u>Auditability of system</u> The software must maintain a detailed audit trail / log of all activities and transactions, including: a) user actions (as per user types) b) transactions c) errors d) system events e) security-related events. Audit trails of all access must be in place DTAC C3.5 The NCSC provides guidance on logging and protective monitoring.	Must

3.1.16	The software should be capable of exporting all logs to a SIEM solution (security information event management)	Should
3.1.17	Non-repudiation The software must ensure that users cannot deny having performed a particular action or transaction. Logs must be tamper proof and monitored for integrity	Must
3.1.18	Resilience The software must be able to withstand and recover from security incidents, such as but not limited to: a) Attacks b) Breaches c) disasters.	Must
3.1.19	Technical If the software facilitates the sending of emails it must be capable of enforcing transmission via TLS 1.2 encryption	Must
3.1.20	The software must only be available via TLS 1.2 encryption (HTTPS) to be applied Using Transport Layer Security (TLS) in your organisation - GOV.UK (www.gov.uk)	Must
3.1.21	Security Testing To identify and mitigate security risks the system must undergo annual or after major change activity, security testing and assessment, including, but not limited to: a) vulnerability scanning b) code review c) external penetration testing The NCSC provides guidance on producing clean and maintainable code . DTAC C3.3 d) The external penetration test must have included the OWASP top 10 vulnerabilities, with the report demonstrating there are no vulnerabilities that score 7.0 or above using the Common Vulnerability Scoring System (CVSS). DTAC C3.2 Please provide evidence you have remediated actions from your last security test.	Must
3.1.22	The provider must be willing to work with the commissioner to assess and remediate all notifications received by the commissioner from the NHS care cert service	Must

3.2 Reliability Requirements

NFR Rationale		
The software must be able to operate continuously without experiencing significant downtime or data loss. Requirements listed below:		
NFR Group Owners		
Graham Sheppard		
Req. Ref	Requirement	Priority (MoSCoW)

3.2.1	<u>Availability</u> The software must be available for use by authorised users and services when required, with a minimum amount of downtime. The RM provider to provide a 99.9% availability agreement which equates to 44 minutes of acceptable downtime per month DTAC 1.11	Must
3.2.2	<u>Resilience</u> To operate with minimal impact on users and data the software provider must be able to withstand and recover from security incidents and other failures and disruptions, such as but not limited to hardware failure, network outages, attacks, breaches and disasters, minimising data loss and restoring system data and functionality <i>Examples of Recovery time objective and Recovery point objective: recovery time objective 3 hours to return the service to a fully functional state following a Provider business continuity event. Recovery point objective 15 minutes of data age prior to the time point of a Provider business continuity event.</i> To be agreed in the final contract award with the Provider as part of the service level agreement	Must
3.2.3	<u>Business Continuity / Disaster recovery</u> The software must be supported by robust business continuity plans and disaster recovery measures.	Must
3.2.4	<u>Redundancy</u> The software must have redundant components or failover mechanisms, to ensure continuous availability and resilience in an event of interruption to single components	Must
3.2.5	<u>Monitoring / Reporting</u> The software provider must have monitoring mechanisms in place, to provide real-time detection and reporting on any: a) Failures b) Errors c) performance issues (response times) d) availability (uptime) The software provider must comply with NHS Service Standard Point 14 regarding operating a reliable service DTAC – D1.12 – D1.12.2	Must
3.2.6	<u>Testing</u> to ensure reliability and resilience The software must undergo rigorous testing and validation, including but not limited to: a) functional testing b) performance testing c) stress testing	Must

3.3 Performance Requirements

NFR Rationale		
The software must be able to perform its functions within acceptable time frames and with minimal impact on other systems or users. Requirements listed below.		
NFR Group Owners		
- Duncan Pike - Graham Sheppard - Keith Gomes Pinto		
Req. Ref	Requirement	Priority (MoSCoW)
3.3.1	<u>Processing of requests</u> The software must respond to user requests within x seconds to ensure that users are able to carry out their daily workload efficiently and effectively	Must
3.3.2	<u>Resource Utilisation</u> To avoid resource exhaustion or contention the software must use system resources efficiently, such as but not limited to: a) CPU b) Memory c) Disk space	Must
3.3.3	<u>Concurrency</u> The software must be able to handle multiple users or transactions concurrently, without deadlocks or performance degradation.	Must
3.3.4	<u>Caching</u> To improve response time and throughput the software must use caching mechanisms to reduce the amount of data retrieval and processing.	Must
3.3.5	<u>Compression</u> To improve performance the software should use compression techniques to reduce the amount of data transmission and storage	Should
3.3.6	<u>Referrals</u> Referrals to be sent and received in fewer than 60 seconds (once sent, can be received via the Remote Monitoring platform in fewer than 60 seconds).	Should
3.3.7	<u>HL7 Feeds</u> The software should support inbound HL7 feeds from multiple services to enable patient registration and integration between referring organisations. DTAC C4.1.1	Should
3.3.8	<u>Patient data to professionals</u> When data is provided by a patient, this must have been fully processed by the Remote Monitoring platform and be available to the professional user on their interface in fewer than 60 seconds .	Must
3.3.9	<u>Clinically Acceptable Performance Level</u> The software is expected to perform at clinically acceptable performance levels. 99% of system transactions are expected to take less than 2 seconds with an exception for image/file uploads, which are expected to be determined by the upload and download size and are expected to be asynchronous.	Must
3.3.10	<u>Performance Monitoring strategy</u> A performance monitoring strategy is to be provided with the software.	Must
3.3.11	<u>Testing</u> To ensure performance meets the specified requirements the software provider must undergo rigorous testing and validation, including but not limited to: a) load testing DTAC – C3.6 b) stress testing c) performance tuning	Must

	The software provider will work with the commissioner to assist with acceptance testing for functionality and performance during implementation and after major upgrades	
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3.4 Scalability Requirements

NFR Rationale		
The software must be able to handle increases in user traffic and data volume without experiencing performance degradation. Requirements listed below.		
NFR Group Owners		
Graham Sheppard		
Req. Ref	Requirement	Priority (MoSCoW)
3.4.1	<u>Vertical Scalability</u> The software must be able to handle an increasing workload by adding more resources to a single server or node, such as but not limited to: a) CPU b) Memory c) Storage	Must
3.4.2	<u>Horizontal Scalability</u> The software must be able to handle an increasing workload by: a) adding more servers or nodes to a distributed system b) distributing the workload across them.	Must
3.4.3	<u>Capacity</u> The software must be able to process forecast volumes of X users, X data records and X transactions without significant degradation in performance or reliability. Remote Monitoring Beds: Current 150. To raise to 450 overall for Dorset by December 2023 Remote management - 8000 in year one and growing by each year	Must
3.4.4	The software must be able to dynamically scale up or down, based on the workload or demand, to optimize resource utilisation and cost-effectiveness.	Could
3.4.5	<u>Elasticity</u> To optimize resource utilization and cost-effectiveness the software must be able to dynamically scale up or down, based on workload or demand to maintain existing software performance	Must
3.4.6	<u>Load Balancing</u> To avoid overload or bottleneck the software must use load balancing mechanisms to distribute workload evenly among multiple servers or nodes.	Must
3.4.7	<u>Partitioning</u> To improve performance and scalability the software must be able to partition data or workload across multiple servers or nodes.	Must
3.4.8	<u>Redundancy</u> To ensure continuous availability and scalability the software must have redundant components or failover mechanisms.	Must

3.4.9	<u>Interoperability</u> To support interoperability and scalability the software must be able to communicate and exchange data with other systems or services.	Must
3.4.10	<u>Performance</u> To ensure user satisfaction and productivity the software must maintain performance levels as the workload and scale increase. As per when software was signed off in commissioning.	Must
3.4.11	<u>Testing</u> To ensure scalability meets the specified requirements the software provider must undergo rigorous testing and validation, including but not limited to: a) scalability testing b) performance testing. Please provide evidence of last performance test	Must

3.5 Usability Requirements

NFR Rationale The software must be easy to use and navigate, with clear and concise user interfaces and documentation. Requirements listed below.		
NFR Group Owners - Crystal Dennis - Duncan Pike - Graham Sheppard - Keith Gomes Pinto		
Req. Ref	Requirement	Priority (MoSCoW)
3.5.1	<u>User Access</u> Users must be able to access the software from their preferred device, operating system or browser. The provider to advise if any device is not accessible	Must
3.5.2	<u>Patient Access</u> Patient users will be able to access the software via a method that is appropriate for them and their access to technology such as (but not limited to): - A mobile App (iOS and Android) - A Web browser - A Telephonic solution (for example, where questions are read out, then either a button can be pressed or voice result inputted by the patient (eg: an IVR)) - Other?	Should
3.5.3	<u>User Interface</u> The user interface must be easy to use, visually appealing, and consistent, to ensure user satisfaction and productivity.	Should
3.5.4	<u>Navigation</u> To help users find information and complete tasks quickly and easily the software must provide clear and intuitive navigation paths.	Must

3.5.5	<u>Help and Documentation</u> To assist users in using the software effectively it must provide context-sensitive help and documentation. Chat function when something is not correct, no more than 2 click from on any screen.	Must
3.5.6	<u>Performance</u> To ensure user satisfaction and productivity the system must: a) Respond quickly. b) Provide real-time feedback.	Must
3.5.7	<u>Convenience and minimal re-engagement</u> The software shall have the ability to collect data of clinical relevance without the need for repeated contacts by professional users once a patient is onboarded. Keeping patient records as up to date as possible. Nudge capabilities to citizen when to complete their form via notifications email / text.	Should
3.5.8	<u>Error Handling</u> To minimise frustration and improve usability the software must: a) Provide clear and meaningful error messages. b) Help users recover from errors.	Must
3.5.9	<u>Auto Save</u> To minimise errors and maximise the ability for professionals to switch between application in their fast paced and often reactive roles, <i>For example: if a professional has a record open [X time], and system is going to time out[?], the changes made by the professional shall be automatically saved.</i>	Should
3.5.10	<u>Time outs for patient users</u> To minimise errors, and enable patients who need more time to use the software, patients shall be allowed 10 minutes per question before the software times out	Should
3.5.11	<u>Consistency</u> To reduce cognitive load and increase usability the software must be consistent in its: a) Design b) Terminology c) Behaviour	Must
3.5.12	<u>Personalisation</u> To allow users to customize their experience and improve usability the software must provide personalisation features, such as but not limited to: a) Preferences b) Settings c) User Profiles	Must
3.5.13	<u>Gamification</u> The patient interface shall be engaging, utilising 'gamification' design principles (e.g. narrativization, engaging visuals, frequent feedback and rewards). Front end requirement. Reporting and data requirement. Feedback from patient	Could

3.5.14	Device qualities • Devices to be well designed, and simple to operate for the user. • Devices to have clear, simple and easy to use instructions. • Ability for the kit to support Wi-Fi or internet access and minimise dead spots. • Bluetooth enabled functionality	Should
3.5.15	Testing To ensure usability meets the specified requirements and user expectations the system must undergo user acceptance testing and validation (NHS Service Standard Point 4)	Must

3.6 Accessibility Requirements

NFR Rationale The software needs to be accessible to users, assisting users where they have disabilities or impairments. Requirements listed below.		
NFR Group Owners • Graham Sheppard • Crystal Dennis		
Req. Ref	Requirement	Priority (MoSCoW)
3.6.1	Keyboard Accessibility To allow users with mobility disabilities to interact with the system without a mouse it must be fully accessible through keyboard navigation.	Must
3.6.2	Screen Reader Compatibility To allow users with visual impairments to access information through speech or Braille output the system must be compatible with screen readers.	Must
3.6.3	Colour Contrast To ensure that users with visual impairments can distinguish between different interface elements the system must have sufficient colour contrast.	Must
3.6.4	Font Size and Type To ensure that users with visual impairments can read text comfortably the system must allow users to adjust font size and type.	Must
3.6.5	Alternative Text To allow users with visual impairments to understand the content the system must provide: - Alternative text for images - Other non-text content.	Must
3.6.6	Audio and Video Transcripts To allow users with hearing impairments to understand the content the system must provide transcripts or captions for audio and video content.	Must
3.6.7	Time limits To allow users with cognitive or physical disabilities sufficient time to complete tasks the system must provide an option to turn off any time limits.	Must
3.6.8	Keyboard Shortcuts To allow users with mobility disabilities to interact with the system more efficiently it must allow users to perform common tasks using keyboard shortcuts.	Must

3.6.9	Multilingual Support To support a global audience and comply with localisation standards the system must support multiple: a) Languages b) Cultures	Should
3.6.10	The software must comply with the NHS' Public Cloud and Internet First Policies NHS Cloud policies and guidance - NHS Digital	Should
3.6.11	Consistency To reduce cognitive load and increase usability for users with cognitive or learning disabilities the system must be consistent in its design and behaviour.	Must

3.7 Interoperability Requirements

NFR Rationale The software must be able to integrate with other NHS systems and external systems as needed, with easy and consistent data capture, and interoperability between systems and care settings (GP IT Futures systems and services - NHS Digital) Requirements listed below.		
NFR Group Owners - Duncan Pike - Graham Sheppard		
Req. Ref	Requirement	Priority (MoSCoW)
3.7.1	Data Exchange Formats To enable interoperability with other systems or services the software must support common data exchange formats	Must
3.7.2	Communication Protocols To enable interoperability with other systems or services the software must support common communication protocols	Must
3.7.3	APIs The software must provide APIs (Application Programming Interfaces) that follow the Government Digital Services Open API Best Practices, are documented and freely available, and which third parties have reasonable access in order to integrate technologies. APIs should adopt generally accepted standards of data interoperability for the NHS or social care, such as FHIR (Fast Healthcare Interoperability Resources) dependent on the use case. DTAC C4.1 and C4.1.1	Must
3.7.4	The software must be compatible with other business and clinical systems or services, in terms of hardware, software, and operating systems - to be defined	
3.7.5	Code All new source code must be open and reusable and published under appropriate licences (12. Make new source code open - NHS digital service manual (service-manual.nhs.uk))	Must
3.7.6	Data Standards The software must adhere to Digital Care Services (DCS) data and information standards and utilise operational and information reference data	Must

	such as clinical terminology, drug database data sets, and organisational to provide consistency of information, in line with Digital Care Services (DCS) Data Standards The software should comply with NHS Digital Clinical Information Standards so that information about the health and care of individuals can be shared and compared across the health care sector, using data that are defined consistently. The software should align to PRSB standards around what information should be recorded and shared.	
3.7.7	<u>Receive and update data based on clinical system data</u> The software shall have the capability to receive and update data for patients on at least a daily basis from clinical data systems (e.g. EMIS, Fortrus, Vision and SystmOne). To maximise data functionality and drive system-wide working practices, structured data should be sent in the first instance, and the data structure should conform to internationally recognised standards. PDF sharing should only be used in the last instance. This may be either directly from the clinical data system provider or via the Discovery Data Service (DDS) or local ICS equivalent. In the event of DDS being replaced, the provider will need to work with the new GP system data extraction provider. The ability to interoperate with personal health records enables relevant information held in personal health records to be surfaced as part of the remote monitoring solution (via GPConnect, Patient Knows Best or NHS App). The ability to push structured coded data back to primary care data systems (e.g. EMIS, Vision and SystmOne) in real time or daily. This capability to write to the GP systems may either be achieved via direct integration with the GP clinical system providers or via a third-party intermediary.	Should
3.7.8	<u>Data migration</u> The software must support the safe and effective migration of data between solutions in line with Digital Care Services (DCS) Data Migration Standard	Must
3.7.9	<u>Data Transformation</u> To enable transformation of data between different formats or structures the software must provide data transformation capabilities.	Must
3.7.10	<u>Software Integration</u> The software must enable integration with other software or services, through standard integration mechanisms, such as but not limited to - ESB (Enterprise Service Bus) - Middleware.	Must
3.7.11	<u>Compatibility</u> The software must be compatible with other systems or services, in terms of hardware, software, and operating systems. Development of the software must have used and contributed to NHS open standards, common components and patterns	Must
3.7.12	<u>Testing</u> The software must undergo interoperability testing and validation, to ensure interoperability meets the specified requirements and standards.	Must
3.7.13	<u>IM1 Pairing Integration</u> IM1 Pairing integration shall be enabled So that there is analytics and prediction modelling • Inter Operability - Close integration with GPs, eliminating the need for double data entry. • Automatic population of patient data	Must

	• Rich set of data points aiding QOF, Research, Clinical Trials and algorithms	
3.7.14	<u>Security</u> To ensure interoperability without compromising security the system must ensure secure data exchange and communication with other systems or services. It must have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2) <u>DTAC C4.3</u>	Must

3.8 Maintainability Requirements

NFR Rationale The software must be designed to facilitate maintenance and upgrades, with clear documentation and error reporting mechanisms.		
NFR Group Owners • Duncan Pike • Graham Sheppard		
Req. Ref	Requirement	Priority (MoSCoW)
3.8.1	<u>Extensibility</u> To accommodate changing business requirements or user needs the software must be designed to enable easy: a) Extension b) Customisation: Provider to detail what can be locally configured / development requests as minor or major changes	Must
3.8.2	<u>Error Handling</u> To enable easy troubleshooting and maintenance the system must have: a) robust error handling mechanisms b) clear and meaningful error messages	Must
3.8.3	The software must allow for administrators to delete / amend / revert data entered in error	Must
3.8.4	The software must be designed to facilitate maintenance and upgrades, with minimal disruption to users and data maintaining the 99.9% SLA	Must
3.8.5	Change and release management The software provider must inform the [commissioning organisation] of any updates or changes to the solution at least x days in advance and any updates / upgrades must minimise disruption to users and data	
3.8.6	<u>Logging and Protective Monitoring</u> To enable easy identification and resolution of issues the software must have logging and monitoring capabilities. Audit trails of all access must be in place	Must

3.9 Quality and Safety Requirements

NFR Rationale Provider meets our Accreditation and safety standards		
NFR Group Owners • Keith Gomes Pinto • Graham Sheppard • Paddy Baker • Duncan Pike		
Req. Ref	Requirement	Priority (MoSCoW)
3.9.1	<u>Quality management plan</u> Provider is to agree the content of a quality management plan inclusive of a test and acceptance plan with the provider prior to service commencement.	Must
3.9.2	<u>DCB0129 compliance and DCB 0160 support</u> Provider can provide assurance in the application of clinical risk management as required under DCB0160, including demonstrating compliance with the DCB0129 process, and providing the safety case report, hazard log and associated documentation. It is expected to support local commissioners and deploying organisations with the DCB0160 process and documentation. The Provider is expected to have a clinical safety officer responsible for clinical safety requirements.	Must
3.9.3	<u>Assessing third party products and devices</u> Provider can demonstrate that its product or service for virtual ward remote monitoring has a defined process for assessing third-party products and evidence that any third-party products have been assessed against all relevant standards (relevant for any plugins or additional devices) – these are then verified through the DCB0129 and the DCB0160 process. Any third-party components embedded in the solution must be maintained in an up to date fashion.	Must
3.9.4	<u>Data controller support</u> Provider supports the commissioner to discharge its legal responsibilities as data controller, to maintain appropriate organisational and technical measures to comply with data confidentiality, integrity and availability, in particular: • Automatically maintain an audit log in the system that is accessible by registered users and the ability for users to run audit reports as dictated by the purchaser. • Fully support and work in collaboration with any purchaser's bring your own device policy (BYOD) in place. • Fully support purchaser to detect, report and investigate personal data breaches, complying with the requirement to report specific breaches to the ICO within 72 hours of becoming aware of such a breach, and to the purchaser within 12 hours of discovery. • D. Support the purchaser to complete a Data Protection Impact Assessment (DPIA) template for the service.	Must
3.9.5	<u>Evidence based</u> Evidence of a peer reviewed study from within the NHS.	Should

3.9.6	<u>MHRA approval</u> All medical devices must comply with the MHRA medical device regulations. In the case that the software platform controls the device and/or processes the raw data, the platform must also comply with the medical device regulations.	Must
3.9.7	<u>QISMET</u> QISMET accreditation (sometimes known as certification) of self-management education interventions against two best practice Quality Standards: QIS 2020 and SS2Q.	Should

4 Standards / Frameworks / Compliance

4.1 Standards

Group Owners			
- Graham Sheppard - Paddy Baker - Duncan Pike			
Ref	Requirement	Priority (MoSCoW)	Owner / Source
4.1.1	<u>NHS Digital Services</u> The provider and software should conform with the principles that guide the design of all NHS Digital Services. Provide evidence	Should	Graham Sheppard, Paddy Baker
4.1.2	The provider and software should conform with NHS Dorset Digital Transformation Guiding principles. Provide evidence	Should	Graham Sheppard, Duncan Pike

Ref	Requirement	Priority (MoSCoW)	Owner / Source
4.1.3	offline mode There shall be provision of an offline mode, enabling RM software users to work offline functionality without interruption if internet connectivity is not available or is lost	Could	Crystal Dennis, Alex Tealdi, Carly Ings
4.1.4	Automatic updates offline to online There shall be Automatic synchronisation of updates made offline when switching from offline to online modes	Could	Crystal Dennis, Alex Tealdi, Carly Ings

4.2 DTAC (The Digital Technology Assessment Criteria)

Ref	Requirement	Priority (MOSCOW)	Owner / Source
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4.2.1	SEE APPENDIX A Document to be completed in full by provider. This will be assessed by Dorset ICB, to further assess how well the solution meets our requirements.	MUST be completed	Graham Sheppard
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4.3 Compliance Requirements

4.3.1	<u>Legal compliance</u> The system must comply with relevant laws and regulations, such as data protection laws, consumer protection laws, or intellectual property laws	Must	
4.3.2	<u>Industry standards compliance</u> The system must comply with relevant industry standards, please attach your certificate. And demonstrate where you exceed a) ISO 9001 (quality management) b) ISO 27001 (information security management).	Must	
4.3.3	<u>Clinical Safety compliance</u> Clinical Safety compliance The system must comply with relevant clinical safety standards (16. Make your service clinically safe - NHS digital service manual (service-manual.nhs.uk), such as but not limited to: a) DCB0129 b) NICE's Evidence standards framework for digital health technologies (to be split out separately) c) Guidance on medical devices from the Medicines and Healthcare products Regulatory Agency (MHRA). d) Other non-mandated standards such as ISO 13485 for quality management systems, ISO 11073 for personal health data, IEC 82304-1 for safety and security for health software, ISO 14155 on clinical investigations for medical devices, ISO/TR 20416 on post-market surveillance for medical devices, BS EN ISO 14971 application of risk management to medical devices, and BS EN 62304 medical device software – software life cycle processes. Evidence standards framework for digital health technologies (nice.org.uk)) Evidence standards framework (ESF) for digital health technologies Our programmes What we do About NICE Provider to confirm whether they have a Clinical Safety Officer in place.	Must	
4.3.4	<u>Accessibility Compliance</u> The software must comply with relevant accessibility standards, policies, and regulations, including but not limited to: a) Web Content Accessibility Guidelines (WCAG) 2.1 Level AA (NHS Service Standard Point 5) DTAC 1.4 b) NHS Internet First Policy DTAC D1.9.1 c) Section 508 of the Rehabilitation Act. The Public Sector Bodies (Websites and Mobile Applications) Accessibility Regulations 2018	Must	

	The software should have an associated published accessibility statement DTAC D1.4.1		
4.3.5	<u>Interoperability Compliance</u> The system must comply with relevant interoperability standards, policies, and regulations, such as but not limited to: a) Service-Oriented Architecture (SOA) principles b) Industry-specific standards. c) ISO/IEEE 11073 Personal Health Data (PHD) Standards (If the system is a wearable device, or integrates with them) d) The solution must support both IPv4 and IPv6 e) If the solution is, or integrates with a personal health device, it must comply with ISO/IEEE 11073 Personal Health Data (PHD) standards f) The solution must use relevant GS1 ID keys and comply with GS1 standards for data elements and barcodes g) Data must be migrated to the new solution in line with Digital Care Services (DCS) Data Migration Standard	Must	
4.3.6	<u>Performance Compliance</u> To ensure acceptable performance the system must comply with relevant performance standards, such as but not limited to: a) response times b) throughput rates	Must	
4.3.7	<u>Security Compliance</u> The software must comply with UK GDPR legislation	Must	
4.3.8	The software must NOT store data relating to individuals outside of the UK, in line with UK GDPR	Must	
4.3.9	The software provider should comply with the National Data Guardian's 10 data security standards	Must	
4.3.10	The software provider should manage their software in line with the National Cyber Security Centres's Security Design Principles	Must	
4.3.11	The software provider must manage their software in line with the NHS Cloud Security Principles	Must	
4.3.12	The software must comply with NHS Cloud First Strategy	Must	
4.3.13	The software must comply with The GP IT Futures (GPITF) Framework	Must	
4.3.14	Please attach the Data protection impact assessment (DPIA) relating to the product DTAC – C2.3.2	Must	
4.3.15	<u>CE Certificate</u> If not registered with the UK government digital marketplace under a current framework agreement, the software provider must hold Cyber Essentials certification at a minimum. The software provider can provide evidence that the organisation holds a current CE certificate from an accredited CE certification body (as a minimum). Ideally, the organisation holds a current Cyber	Must	

	Essentials Plus (CE+) certificate. Best practice would indicate the completion of an NCA accredited penetration test. Cyber Essentials helps organisations guard against the most common cyber threats. The National Cyber Security Centre (NCSC) have published cyber security guidance for small to medium enterprises (SME's). DTAC C3.1 Cyber Essentials scheme: overview - GOV.UK (www.gov.uk)		
4.3.16	The software provider must comply with ISO27001(information security management), and is ISO27001 certified, please attach your certificate.	Must	
4.3.17	To ensure secure processing and storage of data the system must comply with relevant security standards, such as but not limited to: a) Encryption b) access control c) Hosting d) Protection against cyber attack (Providers should hold Cyber Essentials) All traffic traversing the internet should be encrypted using Transport Layer Security version 1.2 or better for secure information e) (The Information Commissioner has published guidance on international data transfers after the UK exit from the EU Implementation Period) Data should be encrypted in transit rest	Must	
4.3.18	<u>Reliability Compliance</u> The solution provider must comply with relevant reliability-related standards, policies, and regulations, including, but not limited to: a) ISO 9001 (quality management) b) ITIL services and assets in line with ITIL practices Please attach your certificates	Must	
4.3.19	<u>Maintainability Compliance</u> The system must comply with relevant maintainability standards, policies, and regulations, such as but not limited to: a) Coding standards b) Software maintenance guidelines c) The solution must use and contribute to NHS open standards, common components and patterns (NHS Service Standard 13) d) The solution provider must implement the solution using agile ways of working and iterate and improve frequently, in line with NHS Service Standards 7 and 8	Must	
4.3.20	<u>Scalability Compliance</u> The software must comply with relevant scalability-related standards, policies, and regulations, such as but not limited to: a) ISO 9126 Service-Oriented Architecture (SOA) principles.	Must	
4.3.21	<u>DSPT (Data Security and Protection Toolkit)</u> Software provider to confirm they are compliant (having standards met or exceeded status) with the Data Security and Protection Toolkit Assessment. Publish standards met as a minimum requirement DTAC – C2.3.1	Must	

4.3.22	<u>ICO registration</u> The software provider must provide the commissioning organisation with details of its ICO registration number and name and contact details of its Data Protection Officer, Information Asset Owner and Information Asset Administrator	Must	
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4.4 Privacy Requirements

4.4.1	<u>Data Minimization</u> The system must only collect, process, and store the minimum amount of personal data necessary for its intended purpose.	Must	
4.4.2	<u>Permission Management</u> The system must obtain and manage user permissions for the collection, processing, and sharing of personal data, in accordance with applicable laws and policies.	Must	
4.4.3	<u>Anonymization and pseudonymization</u> Where possible and feasible the system must use appropriate techniques to de-identify personal data, such but not limited to: a) Anonymization b) Pseudonymization	Must	
4.4.4	<u>Transparency</u> The system must provide clear and concise information to users about the collection, processing, and sharing of personal data, including the purposes, recipients, and retention periods.	Must	
4.4.5	<u>Access and correction</u> The system must provide patients with the following in respect of their personal data: a) ability to access data b) Ability to correct data c) Ability to request deletion of data d) Ability to request restriction of processing of data	Must	
4.4.6	<u>Data portability</u> Where applicable and feasible the system must provide users with the ability to export their personal data in a machine-readable format.	Must	
4.4.7	<u>Data Protection by Design and by Default</u> The system must incorporate privacy considerations into its design, development, and implementation, such as but not limited to use of: a) Data Protection Impact Assessments b) privacy-enhancing technologies.	Must	
4.4.8	<u>Compliance</u> The system must comply with relevant privacy laws, regulations, and policies, such as but not limited to: a) The UK General Data Protection Regulation (GDPR) b) The NHS Cloud Security Principles c) The NHS Service Standard for respecting and protecting users' confidentiality and privacy d) Digital Care Services (DCS) standard for Information Governance e) Data Protection Act 2018	Must	

4.4.9	<u>Training and awareness</u> To promote a culture of privacy and data protection the system must provide training and awareness programs for users and staff on: a) privacy best practices, b) privacy policies c) privacy procedures	Must	
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4.5 Business Continuity Requirements

4.5.1	<u>service continuity and disaster recovery</u> Provider to provide the general approach to service continuity and disaster recovery. The level of fault tolerance that is built into the solution and the recovery time and recovery point objectives of the solution.	Must	
4.5.2	<u>backups</u> The Provider should ensure backups are stored off site from its primary, set out the frequency of activity and the process required to restore services to an agreed recovery point	Must	
4.5.3	<u>Compliance to ISO22301</u> The Provider should be able to provide assurance that effective business continuity plans are in place. Compliance to ISO22301 would be acceptable.	Must	
4.5.4	<u>System back-ups</u> Provider to evidence system back up strategy		
4.5.5	<u>Disaster recovery plans</u> Provider is to maintain and test a disaster recovery and business continuity plan at least annually.	Must	
4.5.6	<u>Service transition plan</u> Provider is expected to maintain a service transition plan in the event of a contractual exit. All transition activities are to be provided free of charge at the end of the contract term.	Must	
4.5.7	<u>Back-up and recovery strategy</u> Provider is to submit a back-up and recovery strategy for the remote monitoring solution.	Must	