



# **Service Guide**

# **Cyril – Remote Patient**

# **Monitoring**



## Contents

Introduction .....	3
Current Challenges across Health and Social Care .....	3
What Is Cyril .....	6
How Does Cyril Work .....	7
Cyril's Functionality .....	9
Key Benefits .....	12
Figure 1: Programme Objectives .....	14
Governance Framework .....	14
Using Data .....	17
Caring for the Environment .....	19
Summary .....	19
<b>Appendix 1: Benefits Realisation Matrix .....</b>	<b>22</b>
<b>Appendix 2: Clinical Safety Case.....</b>	<b>27</b>



## Introduction

In November 2016 NHS England published a new digital strategy which set out its ambitions to drive and deliver sustainable improvements in healthcare utilising technology to digitise services, connect them to support integration and, through these foundations, enable service transformation. The aim of the strategy is twofold:

- To improve the safety of digital technologies in health and care, now and in the future
- To identify and promote the use of digital technologies as solutions to patient safety challenges.

Digital transformation of health and social care is a top priority for the Department of Health and Social Care (DHSC) and NHS England (NHSE). Cyril supports the reform goals identified by:

- preventing people's health and social care needs from escalating
- personalising health and social care and reducing health disparities.

Cyril has been developed in partnership with clinicians to deliver tangible and sustainable benefits to individuals and to the health and social care economy as a whole.

**For the patient:** Cyril aims to provide information to clinical teams to help maintain patients' independence, reduce hospital length of stay and promotes the philosophy that a patient's home is their Hub.

**For the clinician:** With insight into the daily activities of patients, this could help clinicians make quick and confident decisions that could avoid the risk of a patient being readmitted to hospital.

**For the NHS:** Providing such benefits to both patients and clinical staff will help reduce pressure on hospital resources and shall result in significant, identifiable financial savings with return on investment.

**For Cyril Sense Healthcare Solutions:** Be an innovator within the Healthcare industry and add real value to patient outcomes.

## Current Challenges across Health and Social Care

### Pressure Ulcers

- Pressure ulcers cost the NHS more than £20m in litigation last year (Nursing Times 2019)
- Older people are the most likely group to have pressure ulcers. This is especially true for those older than 70, up to a third of whom will have had surgery for a hip fracture. Age alone is not a risk factor. Instead, it is the problems common in older people that are associated with pressure ulceration. For example, hip fractures, faecal and urinary incontinence, smoking, dry skin, chronic systemic conditions, and terminal illness.
- Pressure ulcers in older patients are associated with a fivefold increase in mortality. In addition, in-hospital mortality in this group is 25% to 33% (Grey 2006).



- Pressure ulcers can result in longer lengths of stay in hospitals. One study found that adult patients who develop pressure ulcers had an extended stay of over 4 days (Graves 2005).
- Another study found patients over 75 years of age, who develop a pressure ulcer in hospital, had a 10 day longer stay (Thelson 2012).
- Treating pressure ulcers costs the NHS more than £1.4 million every day (NHS Improvement 2022).
- In the UK, over 700,000 people are affected by pressure ulcers each year. Of these, 180,000 are newly acquired each year.

### Falls

- Up to one in three (3.4m) over 65s suffer a fall each year, costing the NHS an estimated £4.6 million a day, according to new research out today (Monday 21st June) from Age UK, the new force combining Age Concern and Help the Aged.
- Hip fractures are set to cost the NHS an extra £75million a year (Express 2022)
- A third of people over 65, and half of people over 80, fall at least once a year. Falls are the most common cause of death from injury in the over 65s and cost the NHS over £2bn a year and over 4 million bed days. Nearly 9 million, or one in six people in the population in England was 65 or over at the time of the last census, and the figure is forecast to rise by another 2 million by 2021. (Agency, 2017)

### Virtual Wards

- The use of digital innovations – including virtual wards – that allow patients to receive care remotely help towards early discharge or the avoidance of hospital admission all together, has surged mainly due to their use during the pandemic when face-to-face care was limited and alternative ways of delivering care was sought.
- Virtual wards have been hailed by some as a potential way to improve patient flow and reduce workforce pressures (Times 2022)
- Virtual wards are the future of healthcare, designed to allow for greater patient independence, a faster discharge, and to help avoid any health deterioration due to an extended stay on a hospital ward (Group 24)

### Paper Based Care

- Every day, care is held up and patients are kept waiting while an army of people transport and store huge quantities of paper round our healthcare system. Nurses are usually required to complete between eight and 27 forms when assessing a patient, collecting between 150 and 500 data items – a process which can take up to two hours.



- The amount of time spent on completing paper-based documentation detracts from the delivery of hands-on clinical care. With ongoing staffing challenges across health and social care this is time that nursing and medical teams do not have.
- The NHS spends thousands of pounds on the cost of storing and moving paper around the system. The estimated annual cost of paper storage is between £500,000 and £1 million for each Trust – money which could be spent elsewhere. (NHSE)
- The NHS has spent more than £1 billion on storing medical records in England over the past five years. Some Trusts have so many paper files accumulated over decades that they have to rent space in off site storage units. Many still have overflowing basement archives, despite the health services promise to become ‘paper free at the point of care’ (Times 2023).
- Estate within the NHS is constantly challenged with Trust under PFI schemes spending an average £2.5k annually per metre square. Moving from paper based to electronic documentation releases valuable estate currently used for storing paperwork and supports in the delivery of the NHS carbon net zero strategy.

### Capacity

- Compared to other nations, the UK has a very low total number of hospital beds relative to its population. The average number of beds per 1,000 people in OECD EU nations is 5, but the UK has just 2.4. Germany, by contrast, has 7.8. Since 2010, average bed occupancy has consistently surpassed 85%, the level generally considered to be the point beyond which safety and efficiency are at risk. (BMA 2022)
- As many as one in three hospital beds in parts of England are occupied by patients who are well enough to be discharged, with a chronic lack of social care meaning many do not have a suitable place to go. Previous work by the Nuffield Trust has revealed the majority of delayed discharges are down to a lack of social care, be that social care in the patients’ own homes or placements in a care home or NHS funded aftercare (Guardian 2023).
- Statistics for England from September 2022 report a vacancy rate among doctors of more than 7 per cent and a vacancy rate among nurses of almost 12 per cent. The impact that these shortages have is manifold. With a limited number of staff, the overall capacity of the NHS to deliver the quality and quantity of care that people expect becomes limited (NHS England 2022).
- The NHS Long Term Plan has committed to reducing face to face outpatient appointments by up to a third. Using Cyril’s remote monitoring functionality and the information acquired clinicians and carers are supported to make confident and informed decisions regarding the client negating the requirement for individuals to attend face to face outpatient appointments, thus releasing much needed capacity.
- Falls are the number one reason that older people are taken to the emergency department in a hospital and are a leading reason for people to call for an ambulance, accounting for around 10% of all 999 calls. The NHS England average ambulance response time for less urgent 999 calls in March 2023 was 2 hours and 51 minutes. A non-injury fall would normally



fall into the less urgent category. However, research suggests that pressure ulcers form between the first hour and 4 to 6 hours of sustained loading. Therefore, the risk of pressure damage occurring while waiting for an ambulance, especially on a hard floor, is high.

## What Is Cyril

Cyril is an App based system that enables patients and their families, carers and healthcare providers to maintain a holistic view of their well-being through the tracking of disease progress whilst alerting clinicians and carers to any deterioration in their condition. Cyril is compatible with any Smart or Android device laptops and desktop computers the platform is accessed by authorised clinicians, carers and GPs via desktop systems, smartphone or tablet to view patients results to support clinical decision making, clinical caseloads, virtual ward rounds and multidisciplinary team meetings.

Cyril delivers hybrid care technology to improve health and wellbeing for patients. It uses smart sensor technology and IoT to monitor basic routines to provide care givers and healthcare teams with real time information.

Using Smart Sensor Technology Cyril gives access to real-time data for healthcare professionals where different technologies can be plugged in enabling carers and clinicians to have sight of everything all in one place. Cyril provides a holistic picture of the patient health and wellbeing rather than just focussing on specific symptoms or conditions.

Cyril can be seen as a 'basket of goods approach'. This enables a device-agnostic approach that ensures Technology Enabled Care is personalised and outcome focused. Cyril can provide targeted solutions such as supporting with pressure area care management, falls prevention and management, both in an inpatient and community setting, to the provision of a full virtual ward model, enabling the provision of acute care in the patient's own home or usual place of residence, using a needs-based approach which takes into consideration the preferences and capabilities of patients to manage their digitally enabled care at home. Our risk stratification module supports clinicians and carers to identify and manage those most at risk, supporting with care plan development to mitigate.

Our virtual ward model provides healthcare professionals with the assurance that they have all of the information required to safely care for patients at home, allowing for early supported discharge and reduced length of inpatient stay. Cyril supports with the early identification of potential issues recognising declining patients, allowing early intervention and supporting admission avoidance thereby reducing the pressure on Health and Social Care and reducing the cost to the industry from inpatient care, allowing patients to safely remain at home.

Cyril allows the provision of patient centric care with the ability to configure personalised, tailored metrics and requirements for every patient, recognising that every patient is different. When clicking on an individual patient, a summary of information is available via a customisable Dashboard with the full details of each aspect accessed by one click.



We have developed a widget-based system which gives carers and clinicians clarity and control over the data they receive. Any significant changes to routine will be identified early, helping care givers and healthcare teams make quick and confident decisions without making assumptions using either individually configured alerts or notification. Alerts require immediate attention whilst notifications provide information about trends in patient behaviour and highlight deviations over time from the patient's baseline.

Cyril is an integration platform and is fully compatible with key existing GP IT systems, EPR, Shared Care Records etc. It provides a data platform that can provide information at an individual level from digital solutions to inform data-led practice, enables the aggregation of data to effectively manage data across hundreds or thousands of users and identify requirements for intervention and triage needs.

Cyril provides further functionality with our admission and risk stratification, emergency department, critical care and paediatric modules which address many of the paperwork and documentation challenges that impede clinical practice workflows.

## How Does Cyril Work

Cyril has been designed in collaboration with NHS colleagues, utilising smart sensor technology to transmit data to clinicians in real time. It has been built within AWS, utilising the health analytics platform to model outcomes data to provide a more granular and useful patient insights. This is then coupled with generative AI for data, to self-propagate the information, adopting a simplicity principle to define NextGen care.

Data is collected using a combination of discreet sensors placed throughout the client's home, usual place of residence or hospital room, a wearable device' worn around the wrist or attached to the client as a fob, door sensors, a router gateway, IOT cup and jug and any other telehealth devices required e.g. oximetry, glucometer etc. Information is provided in real time allowing intervention as required. Cyril is easy to set up, with no wires and no requirement for Wi-Fi, as it connects via mobile 4G networks. We offer an installation service, however due to the ease of install clients can use our comprehensive user guides to complete self-set up. The individual doesn't have to monitor the data themselves, in fact they will forget the sensors are there all the while vital sign data is transmitted via a secure portal. This means it can be used in numerous healthcare settings for a variety of healthcare needs.

Data is stored securely which means the individual's personal details are protected and only accessible to those people to whom they have given specific permission to review them. For example, clinician, care giver or family.

Cyril is a widget-based system which gives carers and clinicians clarity and control over the data they receive. The application provides a single view of multiple data sources, which are customisable based on the user's preference and is containerised to enable onboarding of an individual or multiple wards whether in an Acute or Virtual Setting.



A summary of information is available via a Dashboard with the full details of each aspect accessed by one click. Any significant changes to routine will be identified early, helping care givers and healthcare teams make quick and confident decisions without making assumptions.

In addition to monitoring a client's vital signs such as BP, pulse Cyril provides holistic information on the clients' general health and wellbeing and deviations from normal behaviours e.g.

- Mobility
- Location
- Falls
- Air quality (CO2, weather, and pollution levels)
- Room temperature
- Visitor tracking
- Bathroom activity
- Hydration
- Nutrition
- Restlessness
- Wandering

An onboarding form is used to collect patient demographics, and in addition enables the clinician to record baseline information, risk stratification and care plans specific to the individual.

Once the clinician/carer has logged in the ward list or patient caseload is displayed. This patient 'list' can be sorted according to clinicians/carer preference e.g. falls risk, bed number, EDD etc.

One click on the required patient opens a customizable dashboard. The Dashboard is a drag and drop widget-based solution, meaning the Clinician can select specific areas of interest. All data can be reviewed over the course of specified time periods i.e. daily, weekly, monthly with clear trend lines demonstrating changes over time.

Cyril provides the user with pre-configured alerts and notifications:

- An alert requires immediate attention e.g. a Patient who has fallen, a long lie fall even with no significant injury has potential long-term consequences, a patient at significant risk of falls has become increasingly restless, a patient requires a position change. Alerts can be configured to notify clinicians if vital signs go above or below pre-configured parameters e.g. oxygen levels below 95%, pulse above 100. System alerts will also be triggered if a patient recording is missed, and alerts can only be stopped by taking affirmative action.
- Notifications provide information about trends in patient behavior and again these are customisable. Notifications highlight deviations over time from the patient's baseline e.g. a % reduction in mobility over a period, increased frequency of bathroom usage over a period of time. Notifications will also be triggered by changes in vitals signs over a period of time e.g. gradual increase in temperature but not yet reaching the level to prompt an alert.

Algorithms enable the application to understand the patient's routine within a 72-hour period, significant changes to routine will be identified early, helping clinician's make quick and confident decisions without making assumptions.





## Cyrils' Functionality

Cyril is fully customisable, and widgets displayed on the dashboard can be configured to meet the requirements of the individual user based on role based and user log in preferences. The most commonly used widgets are detailed below:

### Turning

The combined accelerometer/Gyro provides an overview of the patients' movement and position. A turning schedule is developed during onboarding and completion of the risk stratification tool e.g. Waterlow for patients at high risk. The body map functionality is used to document location if existing pressure ulcers or areas of concern. An alert is triggered when a position change is required and will only be actioned when the combined accelerometer/Gyro detects a position change. The position eg right side, back is detected and documented along with the specific degree of turn. This data provides a fully auditable trail of position changes in line with care plan and provide quality assurance that exceed the current practice of merely documenting that a position change has been made without any associated evidence.

For a patient where the risk of developing a pressure ulcer is considered low, data can be used to highlight a decline in movement necessitating intervention and a review of risk stratification.

### Falls

The falls widget detects increasing levels of restlessness as well as actual falls. Most falls prevention technology provides alerts once a patient is standing. Unless a carer is in the immediate vicinity this is often too late to prevent a fall. Using falls assessment risk stratification and Cyril's learned behaviours algorithms an alert is triggered when a client becomes increasingly restless, allowing intervention to settle the client. An alert is also triggered when the client places pressure on their hands indicating they are trying to stand.

Data on a client's restlessness can be used to highlight times when a client is at increased risk e.g. overnight to allow for appropriate support to be put in place.

Alerts indicating a fall allows for immediate intervention thus preventing the longer-term consequences of a long lie fall and for patients in the community reducing the need for ambulance call outs. Identifying that a patient has fallen at home when no harm has occurred allows for early intervention such as medication reviews, referrals to falls services thereby reducing the risk of the client suffering further falls.

### Mobility

Sensors placed around the individuals' home, usual place of residence or hospital room detect movement throughout the day. Prolonged hours of immobility or changes to usual mobility behaviour can be an indicator of potential risk of deterioration. You will be able to have oversight of when the Patient is most Active Vs Mobile throughout the selected time period required i.e. day/week/month. This will enable the Clinician to have a view on whether the Patient has mobility issues. If mobility issues are detected, a decision can be taken as to whether the individual requires a clinical assessment or whether additional support is required to assess whether the



individual needs mobility aids or adaptations completed within their home or rehabilitative support to improve mobility.

### Bathroom

The Bathroom Widget provides an overview of how many times the client has visited the bathroom Daily/ Weekly/ Monthly, and the average time spent within the bathroom. If the data demonstrates a downward trend, this may highlight that the client is at risk of dehydration, whereas an upward trend could indicate risk of an UTI.

The widget also details changes in humidity within the bathroom identified when a hot tap is running for a period of time. This indicates when the client is washing/bathing/showering. An absence of humidity changes could indicate that the client is not maintaining personal hygiene needs.

### Location

The Location Widget provides the duration of time that the client has spent within each room within their property. Clicking on the Widget will display a timeline of activity. Information can be reviewed to determine whether the client is wandering at night, sleeping in their living room, spending extended period of time in bed etc., all of which could signify a change in care needs.

Using the location widget i.e. kitchen combined with door sensors on the fridge, oven and microwave a picture can be determined on whether the client is managing their nutritional needs allowing for further support to be instigated if required to prevent the consequences of malnutrition.

### Hydration

The hydration widget provides information of how many millilitres of water the client has consumed within a 24-Hour period. This information is captured using the 'Droplet' IOT Cup and is automatically updated within the system. In addition, the cup has the functionality to flash as a prompt to the patient or carer to drink. A target fluid intake requirement can be set by the clinician during onboarding and notifications configured if intake falls below or above this requirement.

Urine output can be measured using the IOT jug allowing a comparison against fluid intake to ensure adequate hydration levels are maintained to reduce the risks associated with dehydration or fluid retention and to support in the prevention of and early detection of potential health problems.

### Additional Widgets

The widgets associated with vital signs recording assessment and other monitoring devices e.g. spirometry are all individually tailored and provide measurements over specified time periods, trend lines and pre-configured requirements for alerts and notifications.

On completion of the observation/assessment using the blue tooth enabled device the system auto updates with the reading reducing the requirement for manual entry.



### Further Modules

Cyril can provide additional modules for clients currently using paper-based assessment and documentation. These modules at present include:

- General adult admission including CVS observation, fluid balance.
- Risk stratification e.g. Waterlow, MUST, frailty index, FRAT.
- Emergency Department
- Critical Care
- General paediatric admission

Reducing the time taken to manually complete multiple documents necessary for care provision allows those time savings to be repurposed back into delivering patient care. Cyril has the ability to make any form electronic with auto population of patient details, electronic signatures, autofill of fluid intake and output using our IOT cup and IOT jug and autofill of observations using our monitoring devices including pulse, temperature, BP, oximetry, weight, BMI as well as functionality associated with risk stratification. By implementing mobile devices, electronic forms and electronic signatures, the barriers to clinical practice workflow efficiency go away releasing staff time to stay inside of the care delivery process. As well as saving precious resources, Cyril can dramatically reduce errors resulting from incomplete documentation, written errors and lost paperwork, it makes clinical handover between shifts efficient and effective, reduces reporting requirements and provides timely information for targeted patient care.

In addition to the benefits detailed above Cyril's integration with EPR systems negates the need for scanning and uploading paper-based forms into a patients record further releasing staff time and saving costs.

### Hardware

The following hardware is available, and requirements are tailored to meet the needs of clients:

- Pulse oximeters
- Thermometers
- Blood pressure Cuffs
- Scales
- ECG Monitors
- Glucometer
- Spirometer
- POC Testing
- Combined accelerometer/Gyro wrist/fob
- PIR Sensors
- Door sensors
- Router gateway
- Hydration – IOT Cup
- Urine Output – IOT Jug

Dashboards are available to highlight device connectivity, location, and battery life and we offer a 24/7 support service, including phone, AI Chat Bot, Email, and ticketing system to deliver a timely and efficient service. All staff are technically trained, and each client is assigned an



Account's Manager, Operational and Clinical Lead to ensure ongoing provision of high quality services.

We have developed simple cleaning protocols for the devices in line with the NHS Code of practice on the effective prevention and control of infection by health service providers.

Maintaining core levels of stock is crucial for ensuring operations run smoothly, therefore, all Equipment that is issued has a RFID tag attached to provide automated inventory management, enabling staff to track the availability and condition of the equipment. The records provide the following information:

- Issue Date/ Return Date
- Maintenance History
- Service Schedules
- Warranty Information

The inventory system contains advanced AI Analytics and reporting tools, providing valuable reports such as asset utilisation, equipment performance, stock levels etc. This data can be used to identify trends, optimise allocation, stocks level and support decision making for equipment procurement.

## Key Benefits

We work in partnership with our clients across primary and secondary care to tailor our product to their needs and implement systems and processes for improved integration and cohesion.

We aim to deliver:

- Prevention and community development – attention to prevention of ill-health and to build community partnerships ensuring a range of support services.
- What matters to me: personalised care – Conversations with our services will start with “what matters to me”. Citizens and their loved ones will be involved in leading their care, with the support of our specialist teams, to make good decisions ensuring they receive care that is right for them.
- Home First – increasing services delivered at home, both face-to-face and digitally, to allow freedom, decrease travel requirement and create efficiency.
- Digitally enabled – embracing technology at the heart of modern life, increasing digital connection across all services.
- Majority of services close to home – increase the services available at Community Health and Wellbeing Centres, Community Hospitals and Diagnostic Hubs for care closer to patients’ homes. We have a sustained track record of investing in community facilities and in doing so, we can provide more rapid access to the right treatments for local people.
- Safe and effective general acute care – continuous improvement of quality of hospital services. Working with service providers to prevent admission and concentrate services on patients who do need a hospital bed.
- Specialist services in partnership – expanding specialist services and partnerships across communities. Ensuring people have the best care, reliably delivered with reduced waiting times.



- Equity of access – overcoming identified regional inequality levels by working tirelessly to improve outcomes using personalised care and designing services around the needs of our community.

Cyril provides key information to enable preventative action to divert people to the proper support and options before they fall into greater need. The benefit of this approach is two-fold. Firstly, citizens can receive the personalised support that they need as early as possible, and before low level need becomes unmanageable. This promotes independence and confidence in the community. Secondly, early intervention releases pressure on the social care system, and provides a redirection, where appropriate, away from contracted care.

Our vision is ultimately to enable the majority of older people, people with disabilities, people with mental health problems and other vulnerable people to live as independently as possible for as long as possible in their own homes. By increasing the use of technology enabled care (TEC) people will be supported to live for longer within their own communities, leading to a reduction in the proportion of adults being supported by residential/nursing provision for lengthy periods of time, and the pressure on the local health economy e.g. by enabling earlier hospital discharge, shorter hospital stays for general conditions and even preventing some hospital admissions.

Existing service provisions no longer meet the full requirements of local populations as populations and their associated health and social care needs continue to grow in both size and complexity. Without the addition of a TEC Service, many citizens would be coming through the front door into Adult Social Care, where the volume of statutory referrals is already highly over capacitated.

The geography and demography of the United Kingdom makes it an ideal environment for technological solutions, but not without challenges. The population is ageing, and digital infrastructure is not widespread.

Five strategic objectives have been identified for provision of Technology Enabled Care Services (TECS) to our clients based on the NHS Framework Outcomes Domains, each with a set of more specific benefits and successful achievement of the outlined objectives will deliver a number of important benefits for our clients and their communities.

In addition, two further key benefits have been identified in support of delivering tangible improvements to the health and social care system (Fig 1).

Figure 1: Programme Objectives



A full Benefits Realisation Plan will be developed in partnership with our client during discovery and implementation and is detailed further in Appendix 1. The full plan will detail the following:

- Scheme Objectives: As defined in Figure 1 above.
- Enabling Objectives: The action(s) required in order to achieve each scheme objective.
- Scheme Outcomes: What benefits will be delivered should the enabling objectives be fully realised.
- Benefits Experienced: A list of quantifiable benefits that will be unlocked through the successful delivery of each scheme outcome.
- Current baseline measurement: current metrics to enable identification of realised benefits.
- Benefit ownership: Who is responsible for delivering these benefits.
- Target date: Clear expectation of time taken to deliver objectives and associated benefits.

## Governance Framework

### Quality Management

We have developed and implemented a Quality Management System Framework to document and improve our practices to exceed the expectations of our customers, stakeholders and interested parties, achieving ISO 9001:2015 status.



We understand that Information is a vital asset both in terms of the clinical management of patients and the efficient management of services and resources. It is therefore vital that information and data are efficiently and safely managed, and that appropriate policies, procedures and accountability provide a robust governance framework for information and data management.

We have established and maintain policies and procedures to ensure compliance with requirements contained in the Data Security and Protection Toolkit and key legislation including:

- Data Protection Act 2018
- EU General Data Protection Regulations (GDPR)
- Freedom of Information Act 2000
- Common Law Duty of Confidentiality
- Caldicott Reviews 1997, 2012, 2016
- Data Security and Protection Toolkit
- Care Quality Commission (CQC) standards.
- Confidentiality: NHS Code of Practice 2003
- Records Management Code of Practice
- Guide to the Notification of Data Security and Protection Incidents 2018

It is recognized that defining, implementing, and documenting our quality management system is only the first step towards fully implementing its requirements. The effectiveness of each process and its subsequent output is measured and evaluated through regular internal audits, quality inspections and data analysis. We use key performance indicators (KPIs) that are linked to our objectives to control and monitor our processes, as well as assessments to determine the risks and opportunities inherent to each process. We use trends and indicators relating to nonconformities, objectives, and corrective action, as well as, monitoring and measurement results, audit results and customer satisfaction data, process performance and the conformity of our products.

### Data Security

Our data platform solution is implemented for and hosted on AWS (Ireland Region) to leverage its comprehensive security and compliance measures, such as, data centre security, data protection and encryption, asset protection and resilience, environment separation, operational security, governance framework, etc. AWS provides its certification details at <https://aws.amazon.com/compliance/iso-certified/>, which includes ISO/IEC 27001:2022. and publishes its Healthcare Compliance in the Cloud White Papers at <https://aws.amazon.com/health/healthcare-compliance/>. The development of our platform primarily follows the [Health and Social Care Cloud Security – Good Practice Guide](#) written jointly by NHS Digital, NHS England, the Department of Health and Social Care and NHS Improvement and the relevant recommendations by AWS.

We use the Health and Social Care Cloud Risk Framework and the [Health and Social Care Data Risk Model](#) for assessing the risks associated with the data and apply controls accordingly. Furthermore, we implement comprehensive monitoring and alerting capabilities to ensure sufficient management of ongoing risks.



Our security and compliance highlights include:

- Shared responsibility model between us and AWS to ensure security and compliance requirements to be met.
- Follow AWS Well-architected Framework, especially the Security Pillar and Resilience Pillar to ensure data protection, resilience, and security controls.
- Deploy dedicated AWS Landing Zone and secure VPCs for each client.
- Apply data encryption in transition and data encryption at rest by default for data protection.
- Employ comprehensive tools, e.g. AWS WAF, AWS Shield, AWS Firewall, for Internet and Interface protection.
- Implement DevSecOps practice and tooling for automation and security testing at every stage of the SDLC.
- Joint responsibility and collaboration with AWS for Vulnerability management and system security patching.
- Employ protective monitoring and incident management process to ensure application health and service continuity.
- Implement role-based and policy-based access control with AWS IAM to ensure personnel security and secure user management.
- Robust Identity and access management solutions for interface (API) access, 3<sup>rd</sup> Party Integration, and End user authentication.
- Implement Service Administration and Auditing capabilities, such as security logging, database activity monitoring, security & compliance alerts, etc.

Furthermore, we implement comprehensive monitoring and auditing capabilities to ensure sufficient management of ongoing risks.

### Clinical Safety Management

We manage clinical safety through integration with Health Organisations and professional bodies and we give particular consideration to integration with the approval of Information Standards and the process by which incidents and risks are managed both internally and in partnership with our clients.

We will seek to integrate with the existing suite of clinical devices where possible, in doing so will confirm devices in situ have compliance with ISO 13458:2016 and ISO 14971:2019. Any additional devices deployed by us will be compliant with these standards, as we deploy only those products that meet the standards outlined.

We have developed a clinical safety case following completion of a hazard log assessment (Appendix 2). The scope of the patient safety assessment and subsequent hazard analysis is restricted to those hazards which relate directly to the implementation and use of Cyril and the requirements of DCB0129 and DCB0160 respectively.

### Risk Management Framework

We define risk and opportunity as ‘something happening that may have an impact on the achievement of our objectives, or which may affect our QMS’. Risk and opportunity management





is a central part of our organization's strategic management. It is the process whereby management teams and risk owners methodically address the risks and opportunities attached to their activities with the goal of achieving sustained benefit within their activity.

Monthly review of our risk register review is undertaken by our Governance Committee to ensure that risks are being appropriately managed, and that the risk data remains accurate and reliable. Continuous systematic and formal monitoring of implementation of the risk process and outputs will take place against appropriate performance indicators to ensure process compliance and effectiveness. Monitoring may take a variety of forms and range from self-assessment and internal audit to detailed reviews by independent external experts.

### Patient/Customer Experience

We strive to identify current and future customer needs, to meet their requirements and to exceed their expectations. We ensure that the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at all management review meetings.

During our presales process we ensure that customer requirements are understood and met. Customer requirements are converted into internal requirements and communicated to appropriate personnel within the organization. Customer complaints and other customer feedback are continually monitored and measured to identify opportunities for improvement. We continually look for ways to interact directly with our customers to ensure that we focus on their unique needs and expectations.

In accordance with our commitment to exceed our customer's expectations, we highlight effective customer communication as an essential element of delivering customer satisfaction. Appropriate handling of customer communication helps to reduce customer dissatisfaction and, in many cases, turn a dissatisfying scenario into a satisfying experience. Customer satisfaction surveys and questionnaires are ongoing throughout the service delivery cycle using feedback to drive our programme of continuous improvement.

Our company website provides details for clients on how to submit, complaints, concerns, or compliments and what to expect following submission.

## Using Data

Each Client is assigned an Account Manager, Operational and Clinical Lead to ensure thorough Performance Analytics is shared weekly. This information is also available to our partners in real time via our online Performance dashboards, information available includes:

- Response Times
- System Availability and Down Plan
- User Feedback
- Review Error logs.
- Clinical/ Operational incident



The real time data enables our Contract Management Team to identify potential issues and make data-driven decisions to optimise the service's performance. Our team can quickly identify quality issues and potential risks enabling us to take corrective actions to ensure a reliable, safe and a sustainable service.

Cyril has the capability to provide service usage reporting with anonymised data, to support optimisation of operational processes. This is undertaken within the system by completing the following activities:

Service Usage Reporting: Gathering data on how our customers use the application, the metrics include:

- Frequency of use.
- Features used.
- Time spent on each on widget.

All data collected is anonymised in line with the Gartner Data Anonymisation, enabling users to collect insights to make informed decisions that improve service efficiency, customer satisfaction, and strategic direction.

Algorithms enable the application to understand the patient's routine within a 72-hour period, significant changes to routine will be identified early, helping clinician's make quick and confident decisions without making assumptions. The predictive data not only enables the provider to offer preventive care but also supports with proactive demand/capacity forecasting and resource allocation optimisation.

Our Data analytical platform is integrated with Power BI reporting, to create predicative analytics and forecast the demand for TEC services across all regions. In addition, will be able to highlight trends patient cohorts based on demographics etc. This will enable us to drive the TEC Strategy, using data analysis to optimise services, improver experience and deliver improved outcomes. All TEC decisions will be evidence-based, enhancing service quality, and help us stay competitive digital landscape.

The data insights will enable enhancements to the user's current services or the development of new services. Therefore, ensuring that care is patient centric, leading to improved user satisfaction, increased engagement, and improved user outcomes. With more granular information and understanding of the populations they serve, health and social care providers are co-designing and delivering services that better respond to people's needs in the right place at the right time, through multiple channels.

The data collected will be used to support with:

- Continuous innovation and service development in partnership with the Authority.
- Purchasing and maintaining devices which accesses the breadth of technologies available in the market and managing the integration of devices and platforms regardless of operating system.
- Data insights will also be developed to be used at a population level to inform future service planning and decision making. Data will be used to drive continuous improvement over the life of the contract.



- Supports a flexible model which adapts over time as culture change and skills development are undertaken in the Authority's workforce,

## Caring for the Environment

In October 2020, the NHS announced their plans to deliver a Net Zero Health Service, we are committed to minimising our environmental impact and promoting sustainable practice in all our operations. We are compliant with all local regulations and strive to always exceed these requirements.

We aim to achieve ISO 14001 in 2024, we are continuing to evaluate our carbon emissions, seeking improvement through partnerships for both travel and IT (our 2 main sources of energy and resource use). Our ambition is to have an employee base utilising technology with a net zero impact by 2030, along with a product which is manufactured in a net zero environment by 2035.

It is our endeavour to not only align with our partners, but exceed target, which in turn will only bolster collective efforts towards the UK net zero target of 2050.

Our company policy, highlights our ways of working, including our ESG impact highlights the need for 'good' data. We are taking steps to gather data, analyse and plan with a goal of sharing good practice with our partners to enhance not only the relationship, but to ensure we are able to continue to fulfil our organisational goals.

We are committed to supporting the communities within which we operate. We believe in the practice of social responsibility and encourage similar behaviour in our employees and suppliers. We support the conservation of the physical environment and the prevention of pollution at our facilities. We proactively comply with all applicable safety, environmental, legal, and regulatory requirements to which we subscribe.

We have detailed above the benefits Cyril provides to organisations to support with their aims to deliver a Net Zero Health service. Using technology to replace paper-based systems and processes. Paper has a high carbon footprint owing to the carbon emissions produced from the production cycle. Organisations can use the CO2 calculator on the Environmental Paper Network website to calculate the amount of carbon emissions created in the production of their current paper usage.

Using Cyril's remote monitoring functionality and the information required support clinicians and carers to make confident and informed decisions regarding the client negating the requirement for individuals to attend face to face appointments further reducing CO2 emissions associated with travel.

## Summary

There are more connected devices in the world today than humans, with the development of new technologies we'll continue to embrace change. Technology is playing an ever more important part in peoples' lives, 'big data' will change decision making processes for health planning. There's an opportunity to not only market the existing TEC Application capabilities but expand into new sectors.



We will work in partnership with Authorities and Users to introduce and test new Devices, exploring new pathways/services. 'Cyril' can be expanded to monitor health plans, providers, ACOs, and senior living communities looking to predict and shape patient health for improved outcomes and cost savings. Early insight into potential risks of deterioration will allow prompt discussion to trigger changes to the care plan.

Prevention and early intervention represent good value for money, implemented at scale help people to avoid poor health and reduce the growth in demand on public services. From online tools to wearable devices, technology is opening new opportunities to monitor health, identify problems and provide tailored support.

The ageing population combined with rising levels of chronic disease has put pressure on care systems. As a result, we're looking to get smart: integrating IoT services into systems to improve care for patients and become more sustainable.

Management of chronic diseases is another challenge; diabetes being the most prevalent, however is one of the easiest to self-manage using IoT devices.

IoT can help the vulnerable build a community of people around them. Our focus is to provide people with the care they need in the most efficient way, blending human interaction with technology. Most people would rather be living active lives, away from care facilities; but they need assurance that they are being guarded, Clinicians want ready, easy access to full patient information and data to understand their patient population and inform new care pathways with tools that enable them to deliver person-centred care. Cyril delivers these requirements.

The data provided by Cyril gives a fully rounded, patient centric picture of the individual to support with:

### **Mental and emotional health**

Supporting the management of active mental disorders and day-to-day stressors to ensure a person's ongoing wellbeing and happiness is maintained. Understanding patterns in behaviour that may indicate changes in mental and emotional health that require intervention e.g. social isolation, patient not getting out of bed, not maintaining personal hygiene and nutritional needs. For many people living with a mental health condition can be painful, exhausting and isolating. People often do not want to burden others with how they are feeling on a day-to-day basis. Cyril allows monitoring without intrusion and allows carers to check in on a person while not checking up on them. It will give people confidence knowing they are being supported while allowing them to work at their own pace and it offers support and reassurance to carers.

### **Physical health**

Ongoing monitoring of physical health, supporting early detection and intervention of physical health changes, giving patients and their carers the tools and information to manage long term conditions in the safety of their own home. System of alerts and notifications to indicate significant deviations from baseline and changing trends e.g. gradual and sustained increase in temperature/blood pressure allowing for early detection and intervention.

### **Healthy lifestyle**

Not all diseases are preventable but a large proportion of deaths, particularly those from coronary heart disease and lung cancer, can be avoided. Health is not only about avoiding disease – diet,



exercise, hydration, and sleep are essential. Cyril provides information to understand patterns in behaviour and support with managing and maintaining a healthy, independent lifestyle.



## Appendix 1: Benefits Realisation Matrix

Scheme Objectives	Enablers required to realise the benefit	Outcomes displayed if benefit realised	Current Baseline Measurement	Who is responsible	Target Date
Preventing people from dying prematurely	<ul style="list-style-type: none"> <li>Training to programme to support in understanding data and how to interpret</li> </ul>	Early detection and intervention preventing escalation of issues			
	<ul style="list-style-type: none"> <li>System config - alerts</li> <li>24/7 call centre and rapid response team</li> <li>Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Reduction in long lie falls and associated consequences			
	<ul style="list-style-type: none"> <li>24/7 call centre and rapid response team</li> <li>Development of triage protocols to manage and prioritise alerts and calls</li> <li>Notifications to indicate deviations from baseline/change in behaviours</li> </ul>	Reduced mortality as a result of: <ul style="list-style-type: none"> <li>- pressure ulcers</li> <li>- falls</li> <li>- hospital acquired infections</li> <li>- sepsis resulting from UTI or above</li> </ul>			
Enhancing quality of life for people with long-term conditions	<ul style="list-style-type: none"> <li>Onboarding form tailored to patient requirements</li> <li>Integration with monitoring devices e.g. oximetry, glucometer</li> <li>Training to programme to support in understanding data and how to interpret</li> </ul>	Improved ability to self-care			
	<ul style="list-style-type: none"> <li>System access by clinical team to monitor disease progression without requirement for OP appointment</li> <li>Clinically agreed baseline and requirements for each patient</li> <li>User profiles - ensure all information available in single dashboard</li> <li>Training to programme to support in understanding data and how to interpret</li> </ul>	Reduction in outpatient attendances			
	<ul style="list-style-type: none"> <li>Clinically agreed baseline and requirements for each patient</li> <li>User profiles - ensure all information available in single dashboard</li> <li>Training to programme to support in understanding data and how to interpret</li> </ul>	Increased confidence in managing condition independently			



Scheme Objectives	Enablers required to realise the benefit	Outcomes displayed if benefit realised	Current Baseline Measurement	Who is responsible	Target Date
Helping people to recover from episodes of ill-health or following injury	<ul style="list-style-type: none"> <li>▪System access by clinical team to monitor disease progression without requirement for IP care or OP appointment</li> <li>▪Staff training to enable data review and interpretation</li> <li>▪Onboarding form tailored to patient requirements</li> <li>▪Integration with monitoring devices e.g. oximetry, glucometer</li> </ul>	Increased wellbeing after hospital discharge			
	<ul style="list-style-type: none"> <li>▪Clarify hardware requirements and install</li> <li>▪Onboarding form tailored to patient requirements</li> <li>▪Integration with monitoring devices e.g. oximetry, glucometer</li> <li>▪Staff training to enable data review and interpretation</li> <li>▪Notification configuration to monitor deviations for baseline/changes in behaviour</li> </ul>	Early supported discharge resulting in improved outcomes i.e. reduction in hospital acquired infections			
	<ul style="list-style-type: none"> <li>▪System config - alerts</li> <li>▪24/7 call centre and rapid response team</li> <li>▪Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Reduced inpatient length of stay			
		Support reablement to accelerate return to independence			
Ensuring people have a positive experience of care	<ul style="list-style-type: none"> <li>▪Patient satisfaction monitoring - welfare calls, questionnaires</li> <li>▪Set up user involvement group for ongoing system development and improvement</li> </ul>	Increased patient satisfaction with the service			
	<ul style="list-style-type: none"> <li>▪Router gateway where limited access/no Wi-Fi available</li> <li>▪Language support</li> </ul>	Reduce inequalities/digital inclusion			
	<ul style="list-style-type: none"> <li>▪Clarify hardware requirements and install</li> <li>▪24/7 call centre/Chatbot - advice and technical support</li> <li>▪User training to ensure system understanding and confidence</li> <li>▪Set up user involvement group for ongoing system development and improvement</li> </ul>	Enhance people's sense of dignity, autonomy and increase confidence			
	<ul style="list-style-type: none"> <li>▪Onboarding form tailored to patient requirements</li> </ul>	Delivery of personalised care plan			
	<ul style="list-style-type: none"> <li>▪Clarify hardware requirements and install</li> <li>▪Onboarding form tailored to patient requirements</li> <li>▪Integration with monitoring devices e.g. oximetry, glucometer</li> <li>▪Staff training to enable data review and interpretation</li> </ul>	Enabling palliative care patients to die at home if desired			



Scheme Objectives	Enablers required to realise the benefit	Outcomes displayed if benefit realised	Current Baseline Measurement	Who is responsible	Target Date
Treating and caring for people in safe environment and protecting them from avoidable harm	<ul style="list-style-type: none"> <li>▪ Clarify hardware requirements and install</li> <li>▪ Onboarding form tailored to patient requirements</li> <li>▪ Integration with monitoring devices e.g. oximetry, glucometer</li> <li>▪ Staff training to enable data review and interpretation</li> <li>▪ Notification configuration to monitor deviations for baseline/changes in behaviour</li> <li>▪ System config - alerts</li> <li>▪ 24/7 call centre and rapid response team</li> <li>▪ Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Early supported discharge into usual place of residence			
		Increase number of patients supported in usual place of residence utilising TEC			
		Reduction in hospital acquired infections			
	<ul style="list-style-type: none"> <li>▪ System config - notification process deviations from baseline/norm</li> </ul>	Reduction in ED attendances/hospital admission for conditions that could be prevented with early detection preventable			
	<ul style="list-style-type: none"> <li>▪ System config - alerts</li> <li>▪ 24/7 call centre and rapid response team</li> <li>▪ Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Reduction in the number of long lie falls in the community			





Scheme Objectives	Enablers required to realise the benefit	Outcomes displayed if benefit realised	Current Baseline Measurement	Who is responsible	Target Date
Supporting the health and social care system to be able to better predict need and demand and manage capacity	<ul style="list-style-type: none"> <li>•User training to ensure system understanding and confidence</li> <li>•Set up user involvement group for ongoing system development and improvement</li> <li>•Process for staff feedback</li> <li>•Role based system access - dashboard tailored for user</li> <li>•Define reporting requirements</li> </ul>	Increased staff satisfaction with the service			
	<ul style="list-style-type: none"> <li>•System config - notification process deviations from baseline/norm</li> </ul>	Early detection and intervention of issues			
	<ul style="list-style-type: none"> <li>•DPIA completed to support system integration</li> <li>•Identification of systems and information requirements</li> <li>•User profiles ensuring access to information required to support decision making</li> </ul>	Improved integration across healthcare systems			
	<ul style="list-style-type: none"> <li>•System config - notification of increased bathroom visits, increased temperature, reduced hydration</li> <li>•Staff training to enable data review and interpretation</li> </ul>	Reduction in ED attendances/admissions due to UTI			
	<ul style="list-style-type: none"> <li>•System config - notification of decreased bathroom visits, reduced hydration</li> <li>•Use of IOT cup</li> <li>•System config - baseline fluid intake requirement, report actual against baseline</li> <li>•Staff training to enable data review and interpretation</li> </ul>	Reduction in ED attendances/admissions due to dehydration			
	<ul style="list-style-type: none"> <li>•System config - alert trigger</li> <li>•24/7 alert response</li> <li>•Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Reduction in ED attendances/admissions due to long lie falls			
	<ul style="list-style-type: none"> <li>•Install rotator</li> <li>•Pressure ulcer risk stratification tool agreed and configured e.g. Waterlow/Braden</li> <li>•Dashboard to support with audit of pressure change activity</li> <li>•Alerts to prompt position change according to risk stratification</li> </ul>	Reduction in specialist nursing time e.g. TVN			
	<ul style="list-style-type: none"> <li>•Risk stratification tools agreed and configured</li> <li>•Staff training to understand how to order patients according to risk</li> </ul>	Prioritisation of workload using risk stratification			
	<ul style="list-style-type: none"> <li>•Clarify use of paper-based systems and configure into system</li> <li>•Integrate with existing devices for auto updates</li> </ul>	Reduced time spent on administration - automated system with live updates and full integration			



Scheme Objectives	Enablers required to realise the benefit	Outcomes displayed if benefit realised	Current Baseline Measurement	Who is responsible	Target Date
Financial benefits to health economy	<ul style="list-style-type: none"> <li>▪ Clarify hardware requirements and install</li> <li>▪ Onboarding form tailored to patient requirements</li> <li>▪ Integration with monitoring devices e.g. oximetry, glucometer</li> <li>▪ Staff training to enable data review and interpretation</li> <li>▪ Notification configuration to monitor deviations for baseline/changes in behaviour</li> <li>▪ System config - alerts</li> <li>▪ 24/7 call centre and rapid response team</li> <li>▪ Development of triage protocols to manage and prioritise alerts and calls</li> <li>▪ Define reporting requirement</li> </ul>	Reduction in purchased domiciliary hours for non-hands-on care			
		Patients able to stay in their homes for longer, delaying or avoiding the need for residential care			
		Reduction in purchased sleep in services			
		Reduction in emergency attendance and hospital admission			
		Reduce respite care			
	<ul style="list-style-type: none"> <li>▪ Clarify hardware requirements and install</li> <li>▪ Dashboard to support with audit of pressure change activity</li> <li>▪ Alerts to prompt position change according to risk stratification</li> <li>▪ System config - alerts</li> <li>▪ 24/7 call centre and rapid response team</li> <li>▪ Development of triage protocols to manage and prioritise alerts and calls</li> <li>▪ Define reporting requirements</li> </ul>	Reduction in litigation costs as a result of falls/pressure ulcers			
<ul style="list-style-type: none"> <li>▪ Clarify hardware requirements and install</li> <li>▪ Dashboard to support with audit of pressure change activity</li> <li>▪ Alerts to prompt position change according to risk stratification</li> <li>▪ Pressure ulcer risk stratification tool agreed and configured e.g. Waterlow/Braden</li> </ul>	Reduction in usage/ costs associated with pressure relieving devices e.g. beds/mattresses				
<ul style="list-style-type: none"> <li>▪ Clarify hardware requirements and install</li> <li>▪ Dashboard to support with audit of pressure change activity</li> <li>▪ Alerts to prompt position change according to risk stratification</li> <li>▪ Pressure ulcer risk stratification tool agreed and configured e.g. Waterlow/Braden</li> </ul>	Reduction in consumable costs associated with wound care for managing pressure ulcers				
<ul style="list-style-type: none"> <li>▪ 24/7 call centre and rapid response team</li> <li>▪ Development of triage protocols to manage and prioritise alerts and calls</li> </ul>	Reduce calls to emergency services				



## Appendix 2: Clinical Safety Case

### Executive Summary

This document provides the clinical safety case to support implementation of Cyril, a remote patient monitoring system. The standard provides information models and implementation guidance which will be used by the Company to develop technical standards for structuring and coding to facilitate the sharing of information in support remote patient monitoring utilising the Cyril platform. The aim is to incorporate ISO27001 standards to facilitate better access and interoperability.

A total of 9 hazards have been identified associated with the implementation of Cyril and are recorded within the Hazard Log (Section 6). Evaluation of the initial risk associated with these hazards has led to a requirement to implement additional risk controls to reduce residual risk to a tolerable level. Provided that the risk controls and other mitigation recorded in the hazard log (Section 6) are successfully implemented, the residual risk associated with the implementation of Cyril is considered tolerable.

### Introduction

In November 2016 NHS England published a new digital strategy which set out its ambitions to drive and deliver sustainable improvements in healthcare utilising technology to digitise services, connect them to support integration and, through these foundations, enable service transformation. The aim of the strategy is twofold:

To improve the safety of digital technologies in health and care, now and in the future

To identify and promote the use of digital technologies as solutions to patient safety challenges

In addition, delivering care to patients within the comfort and safety of their own homes (including care homes) has been enabled by NHSX through the launch of remote monitoring procurement dynamic purchasing system or DPS. The DPS will make it easier for NHS and social care organisations to select and use the right remote monitoring platforms for patients through a needs-based approach, which takes into consideration the preferences and capabilities of patients to manage their digitally enabled care in the home.

### Purpose

The purpose of this Clinical Safety Case Report (CSCR) is to demonstrate that hazards associated with the implementation of Cyril have been identified and the associated risk evaluated. Where the initial risk was judged to be unacceptable, appropriate controls have been agreed to reduce residual risk to a tolerable level.

### Scope

It should be noted that the scope of this CSCR is restricted to consideration of hazards that are directly associated with the implementation of Cyril. Hazards associated with the deployment of any supporting technical solution, software or other system are out of scope and safety cases for their development and deployment must be provided separately.



## Cyril

The Company's data platform solution, Cyril, is implemented for and hosted on AWS (Ireland Region) to leverage its comprehensive security and compliance measures, such as, data centre security, data protection and encryption, asset protection and resilience, environment separation, operational security, governance framework, etc. AWS provides its certification details

<https://aws.amazon.com/compliance/iso-certified/>, which includes ISO/IEC 27001:2022.

The development of the platform follows well-defined HealthCare Cloud Risk Framework and Digital Data Risk Model for workload risk classification and security impact analysis. The design of the platform follows AWS's Cloud Adoption Framework and AWS Well-architected Framework and apply Security by Design and Zero Trust principles to ensure rigorous security and resilience standards.

### **Security and compliance highlights:**

- Shared responsibility model between the Company and AWS to ensure security and compliance requirements to be met.
- Follow AWS Well-architected Framework, especially the Security Pillar and Resilience Pillar to ensure data protection, resilience, and security controls.
- Deploy dedicated AWS Landing Zone and secure VPCs for each client..
- Apply data encryption in transition and data encryption at rest by default for data protection.
- Employ comprehensive tools, e.g. AWS WAF, AWS Shield, AWS Firewall, for Internet and Interface protection.
- Implement DevSecOps practice and tooling for automation and security testing at every stage of the SDLC.
- Joint responsibility and collaboration with AWS for Vulnerability management and system security patching.
- Employ protective monitoring and incident management process to ensure application health and service continuity.
- Implement role-based and policy-based access control with AWS IAM to ensure personnel security and secure user management
- Robust Identity and access management solutions for interface (API) access, 3<sup>rd</sup> Party Integration, and End user authentication.
- Implement Service Administration and Auditing capabilities, such as security logging, database activity monitoring, security & compliance alerts, etc.

The summary above provides some insights into the security position of the Company's' data platform. Auditing and certification are being built into the development plan of the platform. We are fully aware of the cyber security guidelines and best practices, in the context of Health Care domain, set by relevant authorities and agencies, such as ENISA, EHDS, UK NHS, etc.



## **Clinical Safety Management**

We manage clinical safety through integration with Health Organisations and professional bodies. The Company gives particular consideration to the integration with the approval of Information Standards and the process by which incidents and risks are managed both internally and in partnership with our clients.

We will seek to integrate with the existing suite of clinical devices where possible, in doing so will confirm devices in situ have compliance with ISO 13458:2016 and ISO 14971:2019. Any additional devices deployed by us will be compliant with these standards, as we deploy only those products that meet the standards outlined.

## **Hazard Identification and Risk Analysis**

The first step to preventing harm to patients through the use of these standards is to ensure a good development process that results in standards fit for purpose. Activities that have been carried out to clarify and address this potential include:

Initial patient safety assessment

- What could go wrong (hazards), how often (likelihood) and how bad could it be (severity)?
- What are the hazard causes?
- What risk controls/mitigation is already in place?
- What (if any) additional risk controls should be put in place?

Agreement was also reached relating to the transfer of risk (where applicable) to external organisations e.g. those bodies responsible for implementing the standards.

## **Clinical Risk Evaluation**

The scope of the patient safety assessment and subsequent hazard analysis is restricted to those hazards which relate directly to the implementation and use of Cyril and the requirements of DCB0129 and DCB0160 respectively.

## **Risk Evaluation Process**

The clinical risk associated with each hazard was scored based on two factors; the severity/consequence of harm (if the hazard were realised) and the likelihood of occurrence of that harm. For each of these factors the presence or otherwise of existing risk controls/mitigation was considered.

## **Risk Estimation Matrix**

An inherent risk rating represents the level of risk in the absence of a control environment and is arrived at after measuring the likelihood and the consequence of an event occurring. For each impact or risk that is identified, a risk evaluation is undertaken to assign a specific score in order to determine the correct level of action.

The criteria that were used for scoring are provided below. The values obtained for severity/consequence and likelihood were then applied to the following matrix to obtain an overall risk score from 1 to 5, where 5 represents the greater risk.



Risk severity is calculated by multiplying the likelihood by the consequences of risk. The resulting score is then used to prioritise the appropriate level of action.

### Risk Severity

Likelihood of Occurrence (L)	Consequence Rating				
	Catastrophic	Major	Moderate	Minor	Negligible
Certain	25	20	15	10	5
Occasionally	20	16	12	8	4
Probable	15	12	9	6	3
Unlikely	10	8	6	4	2
Improbable	5	4	3	2	1

### Likelihood

Score	Likelihood	Description
1	Rare	May only occur in exceptional circumstances
1	Rare	Will only occur in exceptional circumstances
2	Unlikely	Could occur during a specified time period
3	Possible	Might occur within a given time period
4	Likely	Will probably occur in most circumstances
5	Almost Certain	Expected to occur in most circumstances

### Consequences/Severity

Score	Impact	Quality
1	Negligible	Non-compliance with standard or procedure that can be managed. No patient harm
2	Minor	Developed component or system may not receive approval through assurance process. Minor injury or illness requiring minor intervention
3	Moderate	Failure to manufacture component to meet design, specification, or standards. Moderate injury requiring professional intervention
4	Major	Failure of a major component or system leading to rejection. Major injury leading to long term incapacity/disability
5	Catastrophic	Catastrophic failure of a component to function in either temporary or permanent state. Incident leading to death

### Risk Exposure Score

Score	Colour	Management Control Action (MCA)
1 to 4	Very Low	No mitigation, no action is required, the risk is ALARP. Monitor to ensure that the risk remains tolerable at this level.
5 to 8	Low	Maintain assurance that the risk remains tolerable at this level. Monitor and manage by routine procedures, unlikely to need specific application of resources (managers and key staff).
9 to 12	Medium	Tolerable if the cost of reduction would exceed the improvement gained. Mitigate through management by specific reviews and monitoring of procedures (Managers) but regular monitoring should occur.
13 to 15	High	Tolerable only if risk reduction is impractical or if cost is disproportionate to the improvement gained. Mitigate by implementing controls to reduce the risk to as low as is reasonably practicable. Where this cannot happen, continual monitoring should occur.
16 to 25	Very High	Intolerable, the risk cannot be justified, expect in extraordinary circumstances. Mitigate by ceasing all related activities.

Of the 9 hazards identified, 2 were initially scored greater than 3 and hence it was agreed that additional risk controls should be put in place.

### Clinical Risk Control



Full details of each hazard, the potential consequences and risk controls/mitigation can be found in the attached hazard log however a summary of the risk reduction claimed is provided below:

<b>Summary of Risk Controls and Mitigation</b>			
<b>Hazard</b>	<b>Initial Risk</b>	<b>Risk Controls/Mitigation</b>	<b>Residual Risk</b>
Hardware Failure	6	<ul style="list-style-type: none"> <li>• Sensors have a heartbeat, an alert will be triggered on Help Desk Dashboard If there is no streaming of live data</li> <li>• Staff training to manage routine issues e.g. battery replacement and sensor maintenance</li> <li>• Provision of spare hardware to clients at hubs</li> <li>• 24/7 Service Level Agreement in Place with Sensor Hardware Provider</li> <li>• KPI with hardware provider within 4hrs of failure</li> <li>• Development of chatbot for live support</li> <li>• 24hr helpdesk</li> </ul>	3
User Issues/Understanding	6	<ul style="list-style-type: none"> <li>• System has been designed to provide all Patient's key information at one click.</li> <li>• Clinical Data is transmitted in near Real Time to provide accurate view of the Patient.</li> <li>• Staff training during implementation</li> <li>• Provision of user guides</li> <li>• System User Guide</li> <li>• Website Chat Box</li> <li>• 24/7 Support</li> <li>• Named Point of Contact.</li> <li>• Webpage Q&amp;A</li> </ul>	3
Data Security Breach	2	<ul style="list-style-type: none"> <li>• RDA database in AWS</li> <li>• MFA and data encryption</li> <li>• BCDHS only access pseudonymised data using unique identifier</li> <li>• Role based system access</li> <li>• Annual penetration testing</li> <li>• Monthly system audits</li> <li>• System access controls</li> <li>• Staff training on induction and annually</li> <li>• Business Policies</li> <li>• Data Protection Officer in post</li> <li>• System Access Controls</li> </ul>	2
Lost Hardware	3	<ul style="list-style-type: none"> <li>• Encrypted 2FA</li> <li>• Asset Register</li> <li>• Replacement process with agreed KPI</li> <li>• RFID asset tracking solution</li> </ul>	3
Inappropriate management of FoI Requests	2	<ul style="list-style-type: none"> <li>• Staff training on FoI on induction and annually</li> <li>• All requests for information forwarded to lead care provider</li> <li>• Safeguarding/criminal offence requests forwarded to Caldicott Guardian</li> <li>• Privacy Notice published on website</li> </ul>	2



AWS Failure	3	<ul style="list-style-type: none"> <li>• AWS data back up</li> <li>• Auto back up every 6hrs</li> <li>• Process for client notification</li> <li>• Business Continuity Plan</li> </ul>	3
Cybersecurity Attack	3	<ul style="list-style-type: none"> <li>• Sophos Anti-Virus Software</li> <li>• Staff training inc Phishing emails</li> <li>• Routine Phishing emails testing programme</li> <li>• Annual Penetration Testing</li> </ul>	3
Power Failure	3	<ul style="list-style-type: none"> <li>• Alert when live streaming stops</li> <li>• Process for client notification</li> <li>• Business Continuity Plan</li> </ul>	3
Internet Failure	3	<ul style="list-style-type: none"> <li>• Data continues to stream through router gateway</li> <li>• Data immediately updates once internet restored</li> <li>• Process for client notification</li> <li>• Business Continuity Plan</li> <li>• Provision of router gateway where no access to Wi-Fi</li> </ul>	3

## Summary of Risk Controls and Mitigation

On the basis that the risk controls and other mitigation identified in the above table are satisfactorily implemented, the residual risk associated with all 9 of the hazards scoring 3 or less and is hence considered broadly acceptable.

Tolerability of Residual Risk		
Hazard	Residual Risk	Argument for Tolerability
Hardware Failure	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
User Issues/Understanding	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Data Security Breach	2	The severity of consequences associated with this hazard is low and the likelihood is the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Lost Hardware	3	The severity of consequences associated with this hazard is low and the likelihood is the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Inappropriate management of FoI Requests	2	The severity of consequences associated with this hazard and the likelihood are the lowest level



		possible within the framework. Hence the overall risk score cannot be reduced further
AWS Failure	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Cybersecurity Attack	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Power Failure	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further
Internet Failure	3	The severity of consequences associated with this hazard cannot be reduced, however the likelihood of harm has been reduced to the lowest level possible within the framework. Hence the overall risk score cannot be reduced further

## Hazard Log

A copy of the Hazard Log is attached below:



DCB 0129 Hazard Log (1).xlsx

## Summary Safety Statement

A total of 9 hazards have been identified, associated with the implementation of Cyril and the associated standards, and are recorded within the Hazard Log.

Provided that the risk controls and other mitigation identified in the hazard log (Section 6) are successfully implemented, the residual risk associated with the implementation of Cyril is considered tolerable.

This clinical safety report and hazard log has been reviewed by the Clinical Safety Officer to ensure that all risks, hazards, and strategies are addressed.

## Quality Assurance and Document Approval

The clinical safety work undertaken to support development of this CSCR has been conducted in compliance with the NHS Digital CSMS. This report illustrates how the requirements of DCB0129 have been applied during the development of the standards in the context of an information standard, rather than a Health IT System.

## Configuration Control / Management



Maintenance arrangements for the standards required will be in accordance with the Information Commissioners Office Standards and National Data Guardians 10 Data Security Standards.

## **Release Management**

Every release that is delivered to a health organisation is accompanied by this clinical safety case report and hazard logs are reviewed to identify and mitigate against any new hazards identified with the new release. If a release does not have safety related issues, then a statement to that affect with evidence that the system has been tested satisfactorily will be provided.