Suvera Clinic DCB0160 Clinical Product Risk Management Plan

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0.1	01 July 2025	Template Created & Initial Product Description Added
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Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Yasmin Karsan	Clinical Safety Officer	23 July 2025	1.0
Tim Cooper	Medical Director	23 July 2025	1.0
Ryan Peggs	Technical Director	23 July 2025	1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Pratyusha Mohan	Head of Care and Clinical Safety Officer	23 July 2025	1.0

Related Documents

These documents provide additional information and are specifically referenced within this document.

Doc Reference Number	Title	Version
1	DCB0160 Clinical Risk Management System	1.0
2	DCB0160 Clinical Safety Case Report	1.1
3	DCB0160 Product Clinical Safety Hazard Log - Suvera Clinic	1.1
4	Functional and Non-Functional Testing Strategy	1.0
5	Incident Reporting Meeting Minutes	-
6	Incident Reporting Procedure	1.1
7	Governance Dashboard	-
8	Clinical Product Safety Platform Log	-
9	Configuration Plan	-
10	Training Log	-
11	Business Continuity Plan	1.1
12	Suvera Product Description	0.4
13	Suvera User Manual	-
14	Hazard Identification Workshops	1.0
15	Clinical Guidelines Policy	1.1
16	SCAL IM1	2.0
17	Suvera Clinic Eligibility Criteria	-
18	UCLP Risk Scoring	-
19	Product development lifecycle	-
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Abbreviations

Term	Definitions
ALARP	As Low As Reasonably Practicable
BP	Blood Pressure
CRMP	Clinical Risk Management Plan
EHR	Electronic Health Record
QOF	Quality Outcomes Framework
SWIFT	Structured What If Technique

Introduction

Purpose of Document

The purpose of the Clinical Risk Management Plan (CRMP) is to define the implementation of, and any variation to, the Suvera Clinic application Clinical Safety Management System. It describes how the Suvera Clinic will conduct clinical risk management to ensure patient safety with respect to services provided and the interrelated and interactive activities that will occur to ensure that the Suvera Clinic Application meets the requirements of DCB0160.

In fulfilling this purpose, any variation to the standard practices and procedures to be followed, as defined by the Clinical Risk Management System (CRMS), when performing the activities of the programme are documented here in this document.

This CRMP identifies the means by which the Suvera Clinic Application shall be controlled to ensure that the safety work is of high quality, conforms to the requirements of the CSMS and any specific programme requirements.

This document will be updated when the plan changes in any way as to deviate from what has been committed to deliver. This will be decided by the Suvera Clinic and Clinical Safety Officer and/or Team.

Background to clinical safety standards and requirements

Information standards provide the mechanism for introducing requirements to the NHS, those with whom it commissions services and its IT system suppliers. There are two Information Standards related to patient safety described below. These Standards can be found at: https://digital.nhs.uk/services/clinical-safety/clinical-risk-management-standards

DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

This standard requires health organisations deploying and using new or modified health IT systems to have a structure to manage clinical risks associated with that deployment. The following will give an overview of the system and demonstrate the plan for risk management.

System Definition / Overview

The Suvera platform supports the Suvera care team in delivering the management of specific long-term conditions (LTC) in primary care on behalf of GP practices. This is undertaken by a virtual clinic using SMS, webforms and templates. Patients are sent an SMS to invite them to use the Suvera platform. Once consented they fill out a webform via the patient dashboard.

Patients are reviewed by the care team with resultant clinical decisions undertaken if required. The current service provision spans multiple long term conditions (see below under clinical context).

The solution allows patients with eligible LTC's to remotely submit their clinical data to the Suvera platform. This is reviewed and added to their medical record via their GP practice system. The Suvera technology compiles the data submitted by patients and populates it onto a clinician dashboard for review. Suvera's clinical team reviews the data submitted and codes the data into the practice's EHR. Tasks are created for the care team if further dialogue is required between the clinical team and patients. Further information on the tasks can be found below.

The deployment of the Suvera virtual clinic is designed to be modular and scalable.

Key aspects of the deployment include:

Pre-deployment EHR Analysis and Eligibility Extraction

- Deployment begins with Suvera's EHR analysts conducting an initial extraction from partner GP practices to identify eligible patients based on pre-defined clinical thresholds (e.g., BP ≥140/90 mmHg for hypertension case finding). This structured approach ensures appropriate patient identification aligned with contract requirements. If patients fit into the eligibility criteria they will then be invited to the service via an SMS.

Patient Engagement via SMS and Web App

- Eligible patients are engaged via SMS with personalised links to the Suvera Patient Web App, where they can submit clinical data (e.g., BP, ACT scores, lifestyle data). This remote engagement model is deployed with an emphasis on accessibility and patient autonomy.

Clinician Onboarding and Dashboard Access

- Suvera Care Team members—including pharmacists, GPs, and care coordinators—are onboarded and granted secure access to the Suvera Dashboard, where they manage patients' reviews. The deployment includes role-specific training and user configuration tailored to clinical function.

Integration with Partner EHR Systems

- Where available, IM1 API integrations allow for semi-automated data synchronisation with GP practice systems (EMIS and TPP). If IM1 is not enabled, manual copy-paste workflows are deployed with auditing steps to ensure accuracy. This dual-mode integration ensures deployment is flexible and does not disrupt existing GP workflows.

Partner Dashboard (Planner) Configuration

- GP practices are given access to the Planner Dashboard as part of the deployment. It enables practices to monitor referral status, discharge patients, and track patient cohorts using filters (e.g., month of birth, target area). Data refreshes every two weeks through controlled EHR extracts.

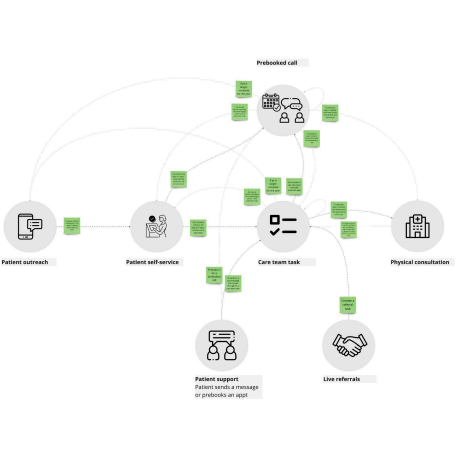


Figure 1 High level overview of the Suvera Clinic

Figure 1 illustrates the functional deployment architecture of the Suvera virtual clinic. This diagram breaks down the end-to-end patient journey and links it to clinical operations. Key components interact with the care delivery workflow to demonstrate how the platform is deployed and used in practice. Further depth is found below:

Central Coordination via “Care Team Task” Node

At the centre of the diagram is “Care team task”**,** which acts as the operational hub of the virtual clinic. It connects all inputs (from patients or systems) and routes them into appropriate clinical pathways.

This node represents:

- The Suvera Dashboard used by clinicians
- The task assignment system for handling patient needs
- Integration points between asynchronous data and synchronous clinical decision

Patient-Facing Deployment Touchpoints

Several patient-facing entry points are shown, demonstrating the multichannel engagement used during deployment:

- **Patient outreach**: Represents the automated SMS invitations sent via Twilio. This marks the first step in deployment when Suvera reaches out to eligible patients.
- **Patient self-service**: Shows how patients can submit health data (e.g., BP, lifestyle) via the Patient Web App, a key part of the virtual clinic's front-end.
- **Patient support**: Indicates support pathways for patients to send messages or schedule calls. This functionality is deployed via secure messaging tools and Acuity calendar integration.

These features are part of the platform's deployment bundle that gets rolled out to GP practices.

Clinical Pathways Enabled Through Deployment

Once a task is created, the care team can direct the patient to:

- **Prebooked call**: A synchronous review via scheduled video or phone call, deployed through Acuity + Google Calendar.
- **Physical consultation**: If remote care isn't sufficient, the system routes patients to an in-person GP practice review with the partner practice**,** showing the safety net built into the deployment model.

GP Practice Partnership Workflow

The Live referrals pathway shows how GP practice staff (via the Planner dashboard) can:

- Refer patients to Suvera
- View progress
- Discharge patients

This supports the co-deployment model where Suvera is embedded within existing GP workflows without disrupting them.

Feedback Loops and Operational Flow

The dotted arrows suggest bi-directional communication and feedback loops, meaning data and actions can flow:

- From patient to dashboard
- From dashboard to patient or GP
- ·From tasks back to scheduling or messaging systems

This reflects how Suvera's deployment is interconnected, rather than linear, ensuring continuity of care.

Aims (Intended Use)

Key clinical benefits

The Suvera virtual clinic is designed to support the remote clinical management of long-term conditions (LTCs) in partnership with GP practices. Its core aim is to enable scalable, safe, and effective deployment of digital-first healthcare pathways that maintain clinical quality while optimising resource use across primary care networks.

Clinical Context

- Seamless remote monitoring of patients with long-term conditions using digital tools, reducing the need for in-person appointments.
- Direct access for patients to communicate with clinicians via pre-booked virtual appointments**,** SMS outreach**,** or self-service clinical updates**.**
- Automated risk stratification and prioritisation, allowing care teams to focus on patients with the greatest need.
- Consistent application of national guidelines (e.g., NICE, QOF) through a digital platform deployed with built-in safety and triage protocols.

Current conditions and parts of care supported are:

The Suvera virtual clinic is deployed to enable the Suvera care team to deliver delegated clinical services on behalf of GP practices, focusing on the proactive management of high-impact LTCs. The deployment includes patient engagement tools, clinician dashboards, and EHR integration, supporting the following clinical workflows (15):

- **Hypertension Case-Finding**
  Patients with elevated BP (≥140/90 mmHg) but not yet diagnosed are invited to submit readings via the Patient Web App. Reviews lead to diagnosis or discharge and are managed via the Care Team Dashboard. This flow is deployed as part of the case-finding onboarding cycle.
- **Hypertension Routine Review**
  Patients already on the QOF register complete digital reviews through the app or a care team call. Care plans are developed and monitored asynchronously, with tasks routed via the dashboard. This service is deployed alongside practice referral criteria.
- **Hypertension Urgent Review**
  Triggered automatically when a submitted BP is ≥175/115 mmHg. These patients are flagged through Slack and reviewed immediately. This alert-driven workflow is part of the deployed high-risk response layer.
- **Diabetes Routine Review**
  Type 2 diabetic patients complete digital submissions; bloods and foot checks are done in-practice. The Suvera care team integrates data from both sources, documents plans, and follows up remotely, using the deployed IM1 (if implemented) and dashboard systems.
- **Diabetes Case Finding**
  Patients with HbA1c between 42–47 are onboarded via the Patient Web App and triaged by clinical rules embedded in the platform. Their care is initiated and documented via the dashboard.
- **Cholesterol Review**
  Conducted as part of a hypertension or diabetes pathway. EHR values are reviewed and addressed via the dashboard. This supports medication review workflows embedded during deployment.
- **Structured Medication Reviews (SMRs)**
  Suvera pharmacists conduct SMRs as part of scheduled reviews using Acuity booking and dashboard documentation. These are deployed as discrete task flows assigned by the care team lead or GP.
- **Frailty Reviews**
  Care team members complete digital frailty assessments using EHR templates and the Suvera Dashboard, as part of the broader LTC workflow.
- **Asthma Reviews**
  Patients complete pre-assessment via the Web App, followed by structured reviews by clinicians. Suvera's digital deployment ensures validated tools (e.g., ACT) are consistently applied.
- **Chronic Kidney Disease (CKD)**
  GFR, ACR and other CKD data are extracted from the EHR and reviewed in Suvera's Dashboard. Deployment ensures data is presented in a structured review format, enabling longitudinal monitoring.
- **·Asynchronous (Async) Reviews**
  Patients previously onboarded can be reviewed without appointments if within validated clinical thresholds. This model is deployed to reduce unnecessary contacts while maintaining safe follow-up. Automated SMS notifications and pharmacist sign-off are included in the deployed workflow.

Users / Scale

- Patient Web App users include:
  - Patients using the web app to submit their Blood Pressure Readings and Lifestyle information.
- Dashboard users include:
  - Suvera Care Team (GPs, IPPs (Prescribing Pharmacists & Care Coordinators).
- Partner Dashboard (Planner software):
  - Staff (GPs, IPPs, Nurses, Administrators) at all/any of our partner GP practices ○ These users are limited to live referrals functionality, as described below.

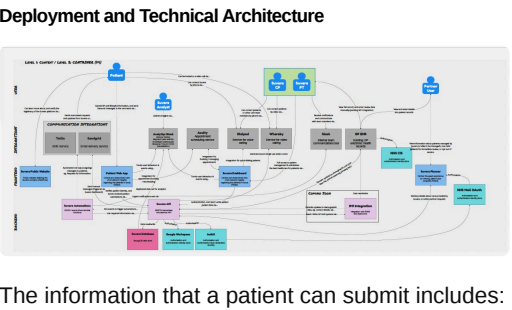
System Functionality Overview

Software Description

The Suvera platform is composed of three integrated components, each designed to support a different aspect of the virtual clinic service:

- **Patient Web App**
  Patients use the web app to securely submit clinical data, such as blood pressure readings and lifestyle information. Once submitted, this information is automatically linked to the patient's profile and made available for review within the Suvera Dashboard.
- **·Suvera Dashboard**
  This is the central workspace for clinicians, enabling them to review patient-submitted data, conduct virtual consultations, document clinical interactions, and manage care plans. It provides a structured, condition-specific view to support safe and efficient clinical decision-making.
- **Planner (Partner Dashboard)**
  Designed for GP practice staff and clinical partners, the Planner offers visibility into the patient population under Suvera's care. It includes features such as real-time task tracking, patient filtering, and the ability to send SMS recalls for follow-up.

Deployment and Technical Architecture



The information that a patient can submit includes:

- Blood Pressure & Pulse
- BMI (height & weight)
- Lifestyle questions
- ACT questionnaire
- Consent for async medication changes

Clinician views in the dashboard

A list of patients

- Name, age, average BP, max bp, status, action ● Patient's Profile
  - nformation submitted by the patient from the webform as above both as a dashboard and as a more detailed complete review.
  - History of encounters with the patient
  - Ability to Log an Interaction
  - Ability to send an SMS to the patient
- Ability to update the action for that patient.

Partner Dashboard

- Show the Target area register patient list
- Sorted by default using (18)
  - Partner EHRs tag patients with their UCLP risk score, once patients are extracted onto planner they sorted with highest risk presented first.
  - Patients without a UCLP risk score are presented at the bottom of the patient list.
- Use filters to switch between Suvera led vs Practice led patient lists
- Ability to filter by
  - Month of birth of patients
  - Practice / Suvera
  - Target area complete/incomplete
- Ability to export filtered data as a csv file. CSV files will not be password protected. However all those with access to patient data will have DBS checks and therefore IG risk is transferred to the practices.
- Data is updated every two weeks in line with EHR extracts
- Show data update notice - see screenshots below - information to show last update of EHR extracts.

Planner

Features

- Finding Patients under Suvera's care
- Finding a Patient under the Practice care
- Export the designated practice patient list
- Viewing Patient interactions with Suvera
- Referring a patient to Suvera
- Discharging a patient from Suvera

The patient list can be filtered by the following categories:

- Target area
- Date of birth
- Suvera status (this is the reason the patient is showing as ‘Your Patient’ rather than a ‘Suvera Patient)

Workflow and Functionality

This section can be found in the Suvera Product Description (12). It summarises the workflow diagrams relating to the main functions of the Suvera Clinic System. It maps expected outcomes by the system and has been used in part to help identify hazards during workshops. The hazard identification workshops consider conditions which may cause deviations to the expected outcomes and possible risks to patient safety. Hazards are evaluated using an agreed categorisation tool and added to the hazard log. This process is explained in more detail later in this document.

Scope / project boundaries

The Suvera Virtual Clinic uses Role based Access control (RBAC) within its deployment.

- Patient Web App users include:
  - Patients using the web app to submit their Blood Pressure Readings and Lifestyle information.
- Dashboard users include:
  - Suvera Care Team (GPs, Clinical Pharmacists, Care coordinators, pharmacy technicians and operations.
- Planner users include:
  - Staff (GPs, Clinical Pharmacists, Nurses, Administrators) at all/any of our partner GP practices
  - These users are limited to live referrals functionality as described below.

System dependencies

Integrations

No integration, but data manually transferred bidirectionally:

- GP EHR - currently manual:
  - See below section for patient registration and sync.
  - Suvera's Care Team members update the EHR in real time to:
    Document in the clinical notes
    Add any necessary coding
    Record patients as discharged from Suvera - this is also communicated to the partner according to agreed local policy - either via task within the GP EHR or by NHS email

Integrated with the Suvera Platform

- Google Workspace: Authentication for Care Team User Authentication
- Twilio: SMS Notifications / Messages. Prompting the patient to make an appointment or complete assigned tasks
- Acuity: Schedule & view Appointments. Acuity is integrated with Google Calendar for Care Team user's to use for scheduled appointments with patients.
- Twilio Send Grid Email API: Send Emails (One-way personalised messages from Care Team to patient via an email button in the platform)
- Slack: for High Risk Alerts / Notifications (i.e. patients submitting S3 blood pressure readings)

Third Party Applications used by Suvera Platform:

- Mongo DB / AWS Stores Data for / from Suvera Platform

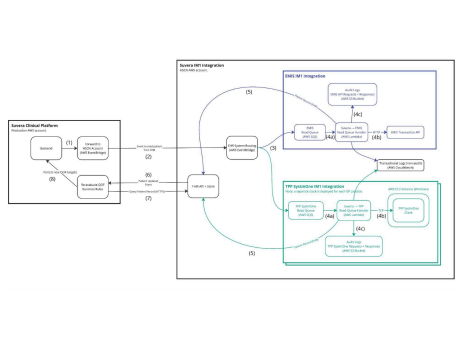
Data Migration

- The Suvera EHR analyst uploads the generated list of eligible patients from the GP's EHR onto the Suvera dashboard.

IM1 Connection

- Ability to read information from the EHR (EMIS and TPP)
- When a consultation is created in the dashboard, it will be sent via the core SDK, which will return a unique ID. By default, it will be visible in the GP practice's EHR within three minutes.
- The care team should have visibility of which GP practices have IM1 integration enabled, so they know if they need to manually copy and paste the consultation or if it will be written automatically.
- When a consultation is created in the dashboard, a grace period of 15 minutes commences. After 15 minutes has elapsed, the consultation gets sent via the core SDK to the EHR.

IM1 Architecture



Product Development Plan

- The Suvera Clinic supports Hypertension, Diabetes, Cholesterol and Asthma.
- The CRMP and the clinical safety activities will be updated as new conditions are added, those new use cases and product enhancements are designed and implemented.

Process for New Releases

The Suvera clinic releases new functionality periodically as per the product development plan. The general process undertaken by the engineering team is detailed below:

- A ticket (relating to the new functionality) is created with:
  - A list of requirements
  - Acceptance criteria
  - A testing plan.
- The ticket is implemented.
- A pull request is opened for review which automatically creates a dedicated test environment for these changes.
- Automated tests run in continuous integration for every change.
- Failing tests block the pull request from being merged (and released into the live production environment).
- All changes are reviewed by another member of the team.
- The changes are validated against functional and non-functional requirements, for example performance, reliability, scalability and usability..
- Depending on the test plan, some manual testing may be performed in a test environment.
- Once the testing is complete and the pull request has been approved, the changes are deployed to the live production environment.
- After release, continuous monitoring will send alerts for any unexpected errors or changes in metrics.
- In addition to post marketing surveillance undertaken by the clinical team.

Impact of DCB0160 on Suvera Clinic

As a healthcare provider deploying and operating digital health systems to deliver virtual care, Suvera Clinic is required to comply with the NHS Digital safety standard DCB0160. This standard applies to health organisations responsible for ensuring the clinical safety of Health IT Systems through proper deployment, use, and maintenance.

DCB0160 sets out the expectations for clinical risk management in the implementation and operational use of digital tools in live healthcare environments. In this context, Suvera acts as the deploying Health Organisation, overseeing the clinical safety of the Suvera platform as used in direct patient care.

Accordingly, Suvera Clinic adheres to all applicable requirements of DCB0160, including the establishment and ongoing management of a Clinical Risk Management File, safety governance processes, and proactive hazard monitoring.

Clinical Risk Management File

The Suvera DCB0160 Clinic CRMF folder in Google Drive location site contains all relevant clinical safety documentation and will perform the function of the Clinical Risk Management File. This folder will be managed by the Clinical Safety Officer.

Resources / Personnel

The Clinical Safety Officer is responsible for ensuring the clinical safety of the products used by Suvera Clinic through the application of clinical risk management. The Clinical Safety Officer for Suvera Clinic is Dr Yasmin Karsan from AnyRx Limited. She is a suitably qualified and experienced clinician who holds current registration with the GPhC and has had appropriate training for this role (NHS Digital Clinical Safety Training in 2023).

Key responsibilities include:

- Approval of the Clinical Risk Management Plan to confirm that the plan is appropriate and achievable in the context of the Health IT System development and modification;
- Ensuring that clinical risk management activities are completed in accordance with the Clinical Risk Management Plan (this document);
- Reviewing and approving of all safety documentation including Clinical Safety Case Reports and Hazard Logs;
- Reviewing evidence in the Clinical Risk Management File to ensure it is complete and supports the Clinical Safety Case Report;
- Providing recommendation to GP Connect Programme whether the Service is safe to release; and
- Escalating any unacceptable safety risks.

Roles and responsibilities

This list includes people who may not be directly involved in the clinical product risk management activities, but are responsible for related activities such as information governance and clinical service etc.

Name	Role	Responsibility
Yasmin Karsan	Clinical Safety Officer	As above.
Tim Cooper	Medical Director	Clinical Governance oversight and Clinical Expertise Responsible for approving the Health IT System and associated safety documentation
Ryan Peggs	Technical Lead	Responsible for ensuring safety design controls are defined and implemented
Rajni Tandon	Governance & Quality Assurance Consultant	Overall Quality Assurance Planning and Advice
Data Protection Simplified	Data Protection Officers	Information Governance and Data Protection
Kaiying Xu	Strategic Partnerships Manager	Product and Service Expertise
Amy Wei-Krkoska	Product Manager	Product Testing & Product Expertise

Clinical Risk Evaluation and Management

The clinical risk evaluation and management process used by Suvera Clinic is in accordance with the requirements of DCB0160, which governs the deployment and use of Health IT Systems within healthcare organisations. The risk matrix and evaluation criteria are outlined below and detailed further in the appendix.

All hazard identification and assessment activities are conducted as part of the implementation and operational oversight of the Suvera platform in live clinical settings. The process aligns with Suvera's Clinical Risk Management Plan, and follows the standard Clinical Risk Management Policy and Procedure defined for health organisations.

In line with DCB0160, Suvera Clinic performs hazard identification through SWIFT (Structured What-If Technique) assessments, focused specifically on the deployment and use of the Patient Webform and Clinician Dashboard across the defined Suvera clinical pathways. The hazard analysis includes a review of operational experiences and any feedback or incidents reported during ongoing live use or pilot phases.

Hazards may also be identified at any stage during the deployment or use of the Suvera platform, including through:

- Feedback or concerns raised during training and onboarding of care teams
- Findings from system configuration or local adaptation prior to rollout
- Incident or near-miss reporting within the live clinical service
- Observations made by Suvera staff, GP practice partners, or other users during routine clinical operations
- Updates or changes to workflows or patient pathways that introduce new risks

All identified hazards are logged, evaluated using the defined risk matrix, and managed through control measures, monitoring, or escalation as required. Residual risks are reviewed regularly to ensure clinical safety is maintained throughout the lifecycle of the deployed system.

For each identified hazard, the following information will be defined and recorded in the Hazard Log:

- Hazard number;
- Hazard name;
- Hazard description;
- Potential clinical impact (Harm) – this will describe the effect of the hazard in the care setting and potential impact on the patient;
- Possible causes (Initiating events) – these may be technical, human, error etc. A hazard may have a number of causes; and
- Sequence of Events - these are the sequence of events that are expected to happen between the cause and the Hazardous Situation that may lead to Harm.
- Hazardous Situation - The situation where the user is exposed to a hazard, that may result in harm to the patient.
- Existing controls – these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation again the hazard, i.e. will be used as part of the initial Hazard Risk Assessment.

The following tasks will be undertaken and the outcome recorded in the Hazard Log

- Estimation of clinical risks;
- Clinical risk evaluation; and
- Clinical risk control option management.

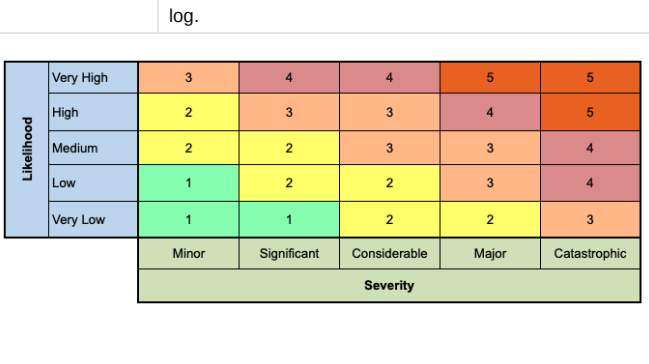
For each identified hazard estimation will be made of the clinical risk. This will include the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. In accordance with DCB0160, Suvera follows the ALARP principle, to reduce risk as far as reasonably practicable. A copy of the risk assessment matrix is provided in the appendix.

Definitions

The following details the definitions used through the hazard log and are key in the categorisation of the hazard. When reviewing hazards, it is useful to have this view. This information is also in the hazard log in addition to the appendix below.

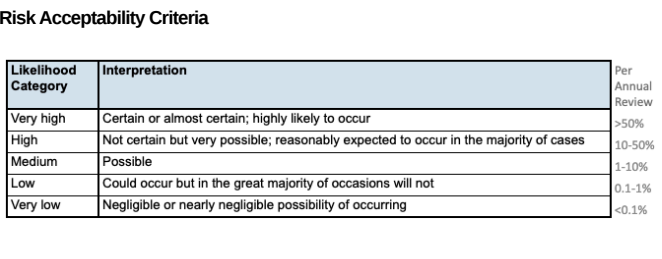
Risk Status

Status Category	Interpretation Status
Accepted	Clinical risk meets acceptability criteria (as defined in risk matrix) or is outweighed by clinical benefits. Risk is ‘as low as reasonably possible (ALARP)’
Monitored	Clinical Risk continues to be monitored, with additional controls yet to be introduced or still under testing
Transferred	Sufficient risk controls have been applied during design and deployment of the system. Further risk management will be undertaken by users specified hazard log.

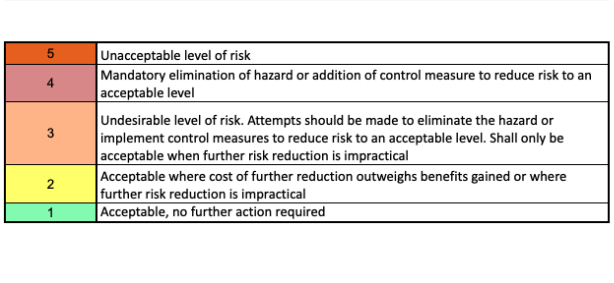


Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

Risk Acceptability Criteria



Likelihood Category	Interpretation	Per Annual Review
Very high	Certain or almost certain; highly likely to occur	>50%
High	Not certain but very possible; reasonably expected to occur in the majority of cases	10-50%
Medium	Possible	1-10%
Low	Could occur but in the great majority of occasions will not	0.1-1%
Very low	Negligible or nearly negligible possibility of occurring	<0.1%



5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level
3	Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

A list of the hazards and their respective risk rating is below and consists mainly of common generic hazards. For details of the hazards please see the hazard log saved in the internal Clinical Risk Management File.

Clinical Product Safety Controls

Where a hazard is assessed as Undesirable or Unacceptable in accordance with the Risk Classification Matrix (see Appendix), Suvera Clinic will identify and implement appropriate risk controls. These controls are intended to reduce clinical risk to an acceptable level or to a level that is As Low As Reasonably Practicable (ALARP), in line with DCB0160 requirements.

Whenever possible, preference will be given to controls that eliminate the hazard at source through changes to configuration, process, or practice.

Types of Risk Controls

The following types of controls may be applied during the deployment and live use of the Suvera platform:

- **Design / Configuration Controls**:
  Adjustments to the system configuration or workflow design at the deployment site to mitigate risk (e.g., enabling alerts, adjusting patient pathways, disabling unsafe defaults).
- **Testing & Validation**:
  Additional testing to verify that the deployed functionality behaves as expected in the live environment, especially where local customisation has occurred.
- **Information & Training**:
  Provision of targeted training to users (e.g., Suvera care team or GP partners) and deployment of user guidance or SOPs to mitigate operational or usability-related risks.
- **Business Process Adjustments**:
  Revisions to clinical or administrative workflows to reduce risk, including escalation procedures, decision checkpoints, or backup manual steps.

Verification of Controls

Once controls have been implemented, the Clinical Safety Officer will review and verify the evidence of their effectiveness. All verified controls will be documented in the Hazard Log, and residual risks will be reassessed accordingly.

Residual Risk

Following implementation of risk controls, each hazard will undergo a residual risk analysis based on the Risk Classification Matrix. The outcome will determine whether the level of risk is acceptable, or whether further action is required

Benefit - Risk Analysis

Where any hazards remain at an Undesirable level after mitigation, and no further practical controls can be implemented, a Benefit–Risk Analysis will be conducted. This analysis will assess whether the clinical or operational benefits of the deployed feature justify acceptance of the remaining risk. If any hazard remains at an Unacceptable level, the deployment process must be paused and reappraised.

Deliverables

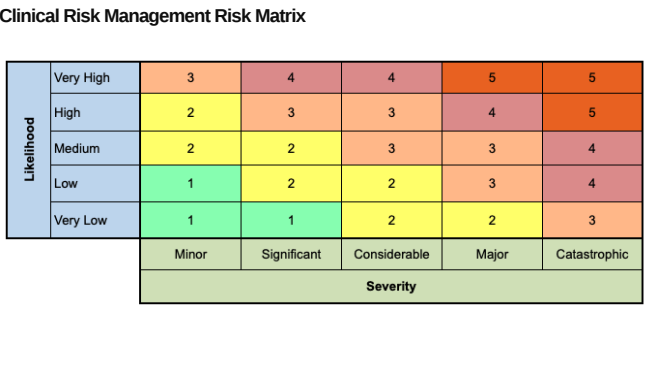
Specific deliverables from the activities described in this Risk Management Plan are:

The following key deliverables support Suvera's compliance with DCB0160 and document the clinical risk management activities undertaken:

- **Clinical Risk Management File (CRMF):**
  Central repository containing all documentation related to clinical risk management for the Suvera Clinic deployment.
- **Clinical Risk Management Plan** *(this document)*:
  Outlines the strategy, responsibilities, and processes followed to manage clinical risk throughout deployment and operation.
- **Hazard Log**:
  A live document capturing identified hazards, associated risk ratings, control measures, and residual risk evaluations.
- **Clinical Safety Case Report**:
  A formal statement that synthesises risk management activities, justifies the safety of the deployed platform, and provides assurance that risks have been identified, assessed, and are being effectively managed.

Appendix – Risk Classification Matrix

Clinical Risk Management Risk Matrix



Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

Clinical Risk Category	Initial Risk (count)	Residual Risk (count)
🟩 Low	2	2
🟨 Moderate	14	11
🟧 Significant	-	-
🟥 High	-	-
🟥 Very High	-	-

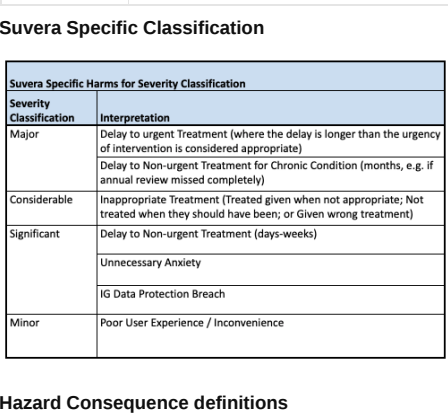
Risk Matrix key - Severity

5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Acceptable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required

Hazard likelihood definitions

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Suvera Specific Classification



Suvera Specific Harms for Severity Classification	
Severity Classification	**Interpretation**
Major	Delay to urgent Treatment (where the delay is longer than the urgency of intervention is considered appropriate)
	Delay to Non-urgent Treatment for Chronic Condition (months, e.g. if annual review missed completely)
Considerable	Inappropriate Treatment (Treated given when not appropriate; Not treated when they should have been; or Given wrong treatment)
Significant	Delay to Non-urgent Treatment (days-weeks)
	Unnecessary Anxiety
	IG Data Protection Breach
Minor	Poor User Experience / Inconvenience

Hazard Consequence definitions

Consequence Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single