DCB0129 Clinical Safety Case Report Suvera Clinic

Suvera

Published 4 August 2025

Document filename: Suvera Clinic Clinical Safety Case Report			
Directorate / Programme	Clinical	**Project**	Suvera Clinic
		Status	Draft
Owner	Yasmin Karsan	**Version**	1.6
Authors	Yasmin Karsan	**Version issue date**	4 August 2025

Document Management

Revision History

Version	Date	Summary of Changes
0.1	26 May 2022	First Draft Started
0.2	26 Jul 2023	Second Draft Started
0.3	31 Aug 2023	Third Draft Started
0.4	20 Sep 2023	Fourth Draft Started
0.5	6 Dec 2023	Fifth Draft Started
0.6	22 Dec 2023	Sixth Draft Initiated
0.7	04 Sep 2024	Reviewed and updated
0.8	18 Nov 2024	Reviewed and updated
0.9	13 Feb 2024	Reviewed and updated
1.0	27 Mar 2025	Reviewed and updated
1.1	15 May 2025	Reviewed and updated
1.2	19 May 2025	Reviewed, updated and Published
1.3	20 May 2025	Reviewed and updated
1.4	02 June 2025	Reviewed and updated
1.5	04 June 2025	Reviewed and updated
1.6	04 Aug 2025	Reviewed and baselined

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Pratyusha Mohan	Head of Care	04 Aug 2025	1.6
Tim Cooper	Medical Director	04 Aug 2025	1.6
Ryan Peggs	Technical Director	04 Aug 2025	1.6

Approved by

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Name	Title	Date	Version
Yasmin Karsan	Clinical Safety Officer	04 Aug 2025	1.6

Version	Date approved	Changes	Approver
1.6	Feb 12, 2026, 00:00	Reviewed and baselined	Pratyusha Mohan

Related Documents

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

Doc Reference Number	Title	Version
1	DCB0129 Suvera Clinical Risk Management System	0.8
2	DCB0129 Clinical Product Risk Management Plan	1.7
3	DCB0129 Product Clinical Safety Hazard Log - Suvera Clinic	2.1
4	Functional and Non-Functional Testing Strategy	0.1
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	-
20	DCB0160 Suvera Clinical Risk Management System	1.0
21	DCB0160 Clinical Product Risk Management Plan	1.0
22	DCB0160 Product Clinical Safety Hazard Log - Suvera Clinic	1.1
23	Standard Operating Procedure	-
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Abbreviations & Definitions

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
PWA	Patient Web Application
LTC	Long Term Conditions
GP	General Practice
BP	Blood Pressure
SMS	Short Messaging Service
Suvera Clinic	Virtual clinic including a patient web dashboard, a care team dashboard and planner.
COPD	Chronic Obstructive Pulmonary Disorder
HTN	Hypertension

Introduction

The purpose of this DCB0129 Clinical Safety Case Report is to provide the structured clinical safety argument, supported by the referenced body of evidence, that the defined Health IT system is acceptably manufactured and safe for its intended use.

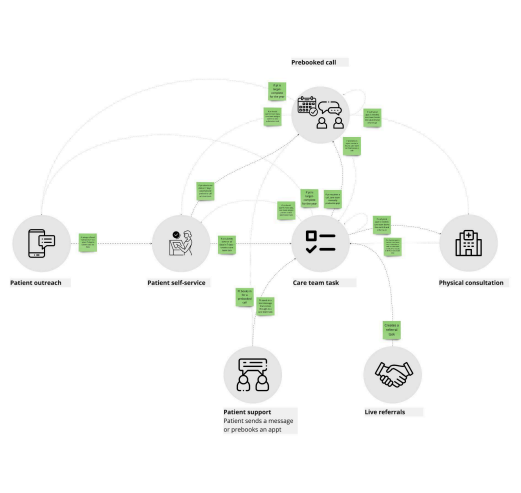
In alignment with Suvera's operating model, which encompasses both development and deployment of the platform, this Clinical Safety Case Report (DCB0129) should be read alongside the DCB0160 Clinical Safety Case Report, which captures the clinical risks and mitigations associated with the system's deployment in live primary care environments.

This Clinical Safety case report demonstrates:

- all risks associated with the system have been identified
- appropriate risk controls have been put in place
- there are appropriate processes in place to monitor the system on an ongoing basis.

System Definition / Overview

The Suvera Clinic supports the Suvera care team in delivering non-urgent management of specific long term conditions (LTC) in primary care on behalf of GP practices. The clinic is comprised of three key components; Suvera Patient Web application, Suvera Dashboard, Suvera Planner. Patient details are obtained from partner practices EHRs. Patients are then contacted via an SMS to invite them to the virtual clinic via a personalised link to their web application. Once consented the web application will ask the patient to submit their clinical data (e.g. BP). The submitted clinical data is accessible by the Suvera Care Team through the Suvera Dashboard. Care team members then invite the patient for a virtual consultation via an SMS. Tasks are generated within the Suvera Dashboard for the Care team members depending on the requirements of the patient (see conditions below). Patients are reviewed by the care team with resultant clinical decisions undertaken by qualified clinicians. Once Suvera's clinical team reviews the patients data, the consultation is coded onto the practice's EHR via IM1. The Suvera clinic is a non-urgent service however on the account where urgent information is processed through the Suvera dashboard, there is an urgent task pathway which notifies care team members to act upon this task within a timely manner. A list of tasks can be found in the Suvera Product Description. The Planner component allows partner practices to review their patients (Suvera and non-Suvera), in addition to sending communications to Suvera clinicians via live referrals. When a live referral is sent via Planner, it shows up on the Suvera Dashboard as a task. A care team member is allocated to these tasks and these referrals are actioned upon (see diagram below).



The overall service is depicted as above and includes the following steps:

- Prior to going live, an EHR data analyst from the Suvera team will go through the GPs EHR. They will extract the full list of patients and run different search criteria, for example blood pressure (BP) ranges (see eligibility criteria). If patients fit into the eligibility criteria they will then be invited to the service via an SMS.
- Patients who require a review are sent an SMS with a link to the Webform. The Webform asks patients to submit self reported clinical information for example BP and lifestyle information dependent on long term condition (see below for further information).
- Members of the care team view and manage patients records as part of a virtual clinic
- Care team members provide a clinical service using the Suvera care team dashboard with access to the practice's EHR for these patients. The consultation summaries are submitted are SNOMED-CT coded onto the EHR by Suvera clinicians
- Data is written directly to the EHR via an IM1 connection. If this fails the care team manually transfers data to the EHR. More information can be found in the product description.

In Scope

The scope of DCB0129 Clinical Product Clinical Safety Case Report and the associated activities is on the manufacturing and use of Digital Health solutions only.

Suvera-developed Digital Health solutions include the Suvera Clinic platform (care team dashboard, planner, patient profiles, and patient web app).

System view of third party Digital Health solutions that are used by the Suveran Clinicians for clinical use in provision of the Suvera Clinic service (tools for Communication integration; Appointment scheduling; Video conference / telephone; GP EHR).

Out of Scope

The clinical governance of the Suvera clinicians running the virtual clinic is managed and assured separately.

The EHR analyst or clinician's interaction with the GP's EHR other than where an error (e.g. transcription error) may occur between the GPs EHR and the Suvera Clinic Platform.

Information Governance and Data Privacy are also not included in the scope of this clinical risk management activity, except where it may impact patient safety. Information governance is managed separately.

Aims (Intended Use)

Key clinical benefits

- Remote monitoring of patient's long term conditions (see list below)
- Patients are able to access clinicians remotely if they have concerns relating to their condition that is under review.

Clinical Context

The Suvera platform supports the Suvera care team in delivering the management of specific long term conditions in primary care on behalf of GP practice.

Current conditions and parts of care supported are:

- **Hypertension case-finding**: review of patients with a recent elevated blood pressure reading (≥ 140/90mmHg) who are not on the QOF Hypertension Register. The review involves patients submitting their blood pressure and lifestyle remotely through the Patient Web App, or on a call with a care team member. The review results in a diagnosis of hypertension or not. If hypertensive they follow the usual hypertension review by a member of the care team or are discharged back to the GP depending on the contract with the GP partner. If their BP is normal, it is recorded that the patient is not hypertensive and then discharged them back to their GP (if nothing is left to do and if they don't belong in another review e.g. diabetes).
- **Hypertension routine review**: Routine review of patients on the QOF Hypertension register. The review involves patients submitting their blood pressure and lifestyle information remotely through the Patient Web App, or on a call with a care team member. A care plan is created and if necessary the patient is followed up until their blood pressure is under control.
- **Hypertension Urgent Review**: As for Hypertension routine review but for patients whose submitted BP is dangerously high (S3). An urgent review is triggered if either the systolic or diastolic numbers of any single reading goes beyond systolic >= 175mmHg or diastolic >=115mmHg. This only relates to patients reviewed routinely. These patients are excluded from live referrals since Suvera can't manage hypertension for patients where most recent blood pressure reading is higher than or equal to 175 systolic or 115 diastolic.
- **Diabetes Routine Review**: Routine annual review of patients with type 2 diabetes in accordance with up to date NICE guidance. Patients submit their blood pressure and lifestyle information remotely and additional diabetes specific information on a call with a Suvera Care Team member. Patients have physical diagnostics (mainly a blood test and foot check) at the GP practice. The results of these are visible to the Suvera care team via the EHR. A care plan is created and if necessary the patient is followed up until their diabetes is under control.
- **Diabetes Case Finding:** If a patient has a latest HBA1c of 42-47 then they are triaged as a diabetes case finding case and managed appropriately.
- **Cholesterol Review:** Currently only performed as part of a hypertension or diabetes review for patients where this should ordinarily form part of these condition reviews - in line with national guidance to bring patient's cholesterol levels and medications under control. Cholesterol levels are accessed via the EHR.
- **Structured Medication Reviews:** Conducting a Structured Medication Review is a key role for pharmacists in all settings as part of the multidisciplinary approach to care. Patients will be booked in to have these reviews.
- **Frailty Reviews:** During the appointment the care team member will be reviewing the patient using the EHR template. The care team member also fills a short frailty template in the clinical dashboard.
- **Asthma Reviews:** Patients are booked in with the care team once the following data is collected via the Patient Web App; Asthma Control Test (Validated), exacerbation assessment, asthma triggers, medication assessment.
- **Chronic Kidney Disease (CKD)**: Patients are reviewed and supported in their management of CKD. Details such as their GFR, ACR and any exception reporting is logged onto the Suvera Dashboard, alongside notes supporting the patient's management of their condition.
- **Async Reviews:** Ability to automatically review patients in relation to the disease areas stated below to indicate if a patient is within QOF guided ranges (see below for validation rules and ranges). If a patient is within ranges the patient could be reviewed async (i.e. without a virtual appointment) via a member of the care team. The patients are sent an editable SMS (see product description) with sign off from the pharmacist. If the patient is out of range, further information or a sync review is needed and an editable SMS can be sent to the patient or a sync review arranged with the patient via a phone call. Async reviews pertain to patients who have already gone through the Suvera intro call and initial consultation route. Therefore patients who enter the async flow via this route are already aware of the Suvera patient web app and process for submitting clinical information.

Users / Scale

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

System Functionality Overview

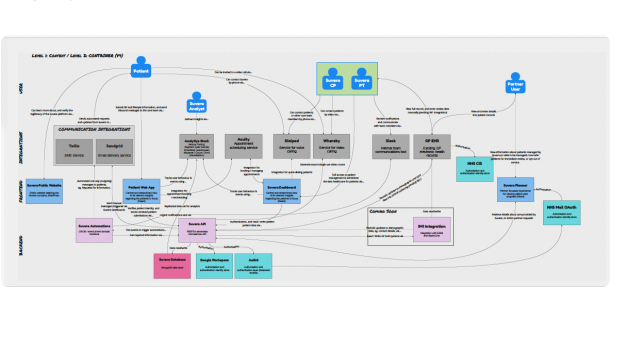
Software Identification

Software Description

The Suvera platform consists of 3 components:

- Patient Web App
  - Patients submit their clinical data via the patient web app.
  - This data is transposed to the Suvera Dashboard under the relevant patient profile.
- Suvera Dashboard
  - The Suvera Dashboard enables clinicians to consult with patients. See product description for further details)
- Planner
  - Enables Partners to have visibility on patients and tasks.
  - Ability to send live referrals

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
  - Information 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.

Planner

Core 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)

In depth features:

- Show the Target area register patient list
- Sorted by default using UCLP risk
  - 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.

Workflow and Functionality

This section can be found in the Suvera product description. 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

- 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

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 users 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

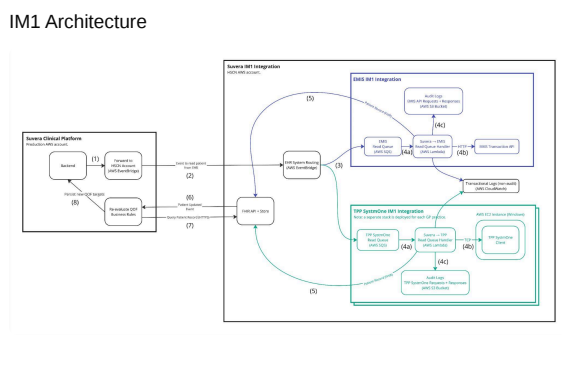
Data Migration

- 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



IM1 Failure Pathway

- 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

Clinical Risk Management System

This product and the safety documents created will follow the risk management processes that are detailed in the existing Clinical Risk Management System.

This approach will ensure compliance with the clinical risk management standards DCB0129 which are mandated under the Health and Social Care Act 2012.

As Suvera also manages the deployment of the product into primary care, a separate DCB0160 Clinical Risk Management System and associated documentation have been developed. Cross-referencing is maintained between these two safety cases to ensure continuity and traceability of clinical risk management throughout the product lifecycle.

The Suvera team and its clinical safety officer are responsible for the creation and and the maintenance of this document, the hazard log and meeting records held as input and assessment of the hazards identified.

Table 1 Roles and responsibilities

Dr Yasmin Karsan	*Clinical Safety Officer (CSO)*	*Write Clinical Risk Management Plan* *Write and Maintain Hazard Log* *Write Clinical Safety Case Report* *Provide Clinical Safety Advice and Recommendations*
Ryan Peggs	*Technical Lead*	*Engineering management and knowledge* *Liaise with product development team*
Ivan Beckley	*CEO*	*Authorise Release for live Service*

Clinical Risk Analysis

To simplify the document, a number of decisions have been made related to the way clinical safety is progressed throughout the project and these are:

- Identification and analysis to identify the hazards will primarily use the SWIFT method
- Assessments of all hazards will be periodically reviewed, and outcomes documented
- Any hazard with an overall risk rating of "Moderate" or above will need to be examined and acceptable control measures identified to bring the overall risk rating to as low as reasonably practical.
- Any hazard with an overall rating of "Low" that has not required a control measure will be accepted
- Definitions of Risk Status, Consequence and Likelihood are documented in the Clinical Risk Management Plan.
- Risk Acceptability Criteria is documented in Risk Acceptability Criteria
- Risk Matrix is documented in this document's Risk Matrix section

The clinical risk matrix, evaluation and management process used is found in the appendix.

Identified hazards captured in the SWIFT workshop meeting notes were transferred to, described and risk rated in the Hazard Log and the following information was defined, recorded and summarised:

- Hazard number;
- Hazard scenario name;
- Hazard description (Cause, Sequence of events, Effect, and Harm). The Hazard is used to classify the hazard scenario equating to the main root cause.
- Existing controls – if any, these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation against the hazard

The detailed results of the SWIFT workshops are documented in the DCB0129/0160 drive.

Clinical Risk Evaluation

For each identified hazard, an estimation was made of the clinical risk. This included the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process followed is that established by the safety processes defined in DCB 0129. A copy of the risk assessment matrix and risk acceptability criteria is provided in Appendix A.

All identified hazards were evaluated from the perspective of patient safety consequences using a Cause, Effect, Hazard, Harm approach to explore potential consequences. Contributory factors were considered, in addition to identifying existing mitigating controls from a Health IT design, User Training and Business Process perspective.

Based on all of the above and using the pre-defined criteria in Risk Matrices (Appendix A) an estimation of Clinical Risk was completed.

Clinical Risk Control

Initial Risk Evaluation

This table shows the initial risk rating prior to sufficient control measures.

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

Residual Risk Evaluation

Following confirmation of completion of controls outlined in the hazard log, the number residual risks are summarised below:

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

Current Status of Residual Hazards

	Status of Residual Hazards				
Status	Acceptable	Acceptable where cost of reduction outweighs benefits	Undesirable level of risk	Mandatory elimination of hazard	Unaccep
Accepted	0	0	0	0	0
Monitored	1	10	0	0	0
Transferred	0	2	0	0	0
Subtotal	1	12	0	0	0
Total	13				

Risk Review

As part of the development ("manufacturing") of the Suvera platform, a total of 13 clinical hazards have been identified and documented. These reflect known risks associated with system design, software functionality, data processing logic, and technical interoperability with other systems.

Of the 13 hazards:

- 10 hazards are actively monitored as part of Suvera's development lifecycle. These include risks such as software bugs, logic errors, and issues with data flow or integrity. These hazards are considered undesirable but manageable due to the implementation of robust control measures, including automated test suites, design validation processes, and regular code audits.
- 2 hazards have been transferred to third-party providers responsible for external systems or services (e.g., EHR integration components or cloud infrastructure). Appropriate mitigation responsibilities have been established in accordance with supplier agreements.
- 1 hazard is accepted, having been assessed as low-risk and outweighed by the platform's clinical benefits. It remains under periodic review.

Mitigating actions include automated testing (unit, integration, and end-to-end), peer-reviewed code changes, structured validation checks, and incident reporting mechanisms embedded in the development workflow. All hazards are tracked and reviewed in alignment with Suvera's Clinical Risk Management Plan, and any material change in functionality or system design will trigger re-assessment.

Full details of each hazard, including classification, controls, and current status, are available in the product hazard log maintained under DCB0129.

Hazard Log

The Hazard log can be accessed here. The DCB0129 Hazard Log includes hazards from the manufacturing phase. Where applicable, these hazards are further monitored and managed in the DCB0160 Hazard Log, particularly if they present deployment implications.

Hazard ID	Hazard	Initial Risk	Residual Risk
HAZ-001	Missing patient or clinical data	2	-
HAZ-002	Incorrect or outdated data presented on the dashboard	2	-
HAZ-003	Data inaccessible	2	-
HAZ-004	Patient receives incorrect or delayed care due to unavailability of clinical information	2	2
HAZ-005	Patient recieves incorrect communication	2	2
HAZ-006	Patient is confused about who Suvera is or what the service is for, leading them to disengage or misuse it	2	2
HAZ-007	Patient's appointment or task is missed because of an issue with a third-party system or integration	2	2
HAZ-008	Urgent clinical information not triaged appropriately	2	2
HAZ-009	Global IT outage	1	1
HAZ-010	Patient can submit data on behalf of another patient	1	1
HAZ-011	Patient recieves in adequate care due to calculations within the dashboard	2	2
HAZ-012	Patient faces critical information missing, which could delay or prevent necessary action.	2	2
HAZ-013	Patient faces a system failing to properly disconnect from outdated records, creating risks.	2	2
HAZ-014	Patient faces care being affected by missing system features or unresolved bugs.	2	2
HAZ-015	Patient faces delays or failures in updates to national systems like Spine, without being notified.	2	2
HAZ-016	Patient faces their information being accidentally added to another patient's record.	2	2

Test Issues

Summary of any outstanding test issues and the impact on clinical safety:
There are currently no outstanding test issues impacting clinical safety. Changes have been implemented as highlighted by the hazard log to mitigate any identified risks.
All functionality in the applications is covered by fully automated testing.

This testing covers all aspects of:

- Security testing (eg attempting to access data when not logged in, or without access)
- Functionality testing (expected functions eg. Log consultation work as expected and result in Correct data being saved for the inputs provided)
- Safety testing (part of functionality testing, but check clinical parameters at all thresholds and boundaries - eg, BP classification etc)
- Sequence testing (larger e2e tests that simulate patient and/or clinician behaviours over multiple day flows)

We currently have these tests:
4224 tests for the shared application backend
1710 tests for the care dashboard UX
670 tests for the partner dashboard UX
285 tests for the patient web app UX

These tests are co-designed by product, clinical and engineering teams and implemented and tested as part of the release process.

We are practice test-driven-development so we write tests first (they will fail because the app/feature doesn't exist) and then build the feature and use the tests as assertions on behaviour being complete to spec.

If any test fails there are technical barriers in place to prevent the corresponding version from progressing to release. All releases also require manual review by an engineer who is not the main author of the release.

Further information on testing can be found here.

Medical Device Status

Suvera has considered whether this application would come into scope for the Medical Device Regulations (MDR). Following guidance from MHRA's Medical device stand-alone software including apps guidance this software component is not classified as a medical device.

This computer program does not have a medical device intended purpose. It does not function to prevent, diagnose, monitor or treat disease. It has no in vitro functionality.
This position will be reviewed periodically.

Summary Safety Statement

The Suvera platform supports the Suvera care team in delivering the non-urgent 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 web app. Patients are reviewed by the care team with resultant clinical decisions undertaken if required. The current service provision spans various long term conditions (see below under clinical context).

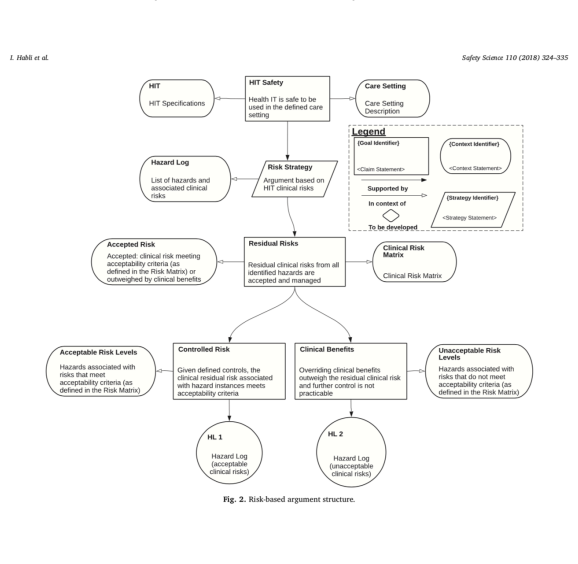
The solution allows patients with eligible LTC's to remotely submit their clinical data to the Suvera platform. This is reviewed and added to their medical record via their GP practice system. The Suvera technology compiles the data submitted by patients and populates it onto a clinician dashboard for 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. Although the Suvera clinic is a non-urgent provider, urgent clinical data may pass through the system, via the live referral route. The Suvera clinic dashboard has built in functionality to process urgent clinical data, in addition to the Suvera care team being trained in acting on urgent queries within a timely manner to mitigate any risk surrounding urgent queries.

The intended use of the Suvera platform and its hazard log has been reviewed. Sufficient hazard identification, evaluation and controls have been completed for the application. These have been subject to rigorous internal and external testing.

The Suvera platform has been taken through witness testing with system supplier(s) and there were no issues raised during this testing series. The status of the majority of the hazards are monitored as we continue to monitor the clinical risk.

In light of the above, I am content that the Suvera Platform has had sufficient clinical risk management activities undertaken. The artifacts of the clinical risk management process, including this document will be reviewed following any further changes in scope, incidents or developments and otherwise routine intervals.

Dr Yasmin Karsan | Clinical Safety Officer | GPhC: 2080112



Quality Assurance and Authorisation to Proceed / Release

All new system requirements follow the change management process as outlined in the clinical risk management documentation. Suvera follows a stringent development methodology to ensure new features are risk assessed, tested and evaluated prior to release, in addition to post marketing surveillance undertaken through governance and platform support portals.

Configuration Control / Management

An implementation / deployment strategy, including configuration guidance and control management has been developed and adhered to as per company documentation.

Reference Documents

The referenced documents collectively form a comprehensive framework for ensuring the safety, and effective operation of Suvera's digital clinical product. Risk identification and management is covered in the following documentation: Clinical Risk Management System, Product Clinical Safety Hazard Log, ongoing safety monitoring is focussed within the Incident Reporting Procedure. Governance and oversight are supported by the Governance Dashboard. The Business Continuity Plan addresses operational resilience and staff preparedness. User-oriented resources such as the Suvera Product Description, User Manual, and Eligibility Criteria ensure clarity and usability, and the Product Development Lifecycle and Hazard Identification Workshops demonstrate a proactive approach to continuous improvement and safety-by-design. Overall, these documents reflect a robust clinical governance and product safety infrastructure.

Appendix A

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.

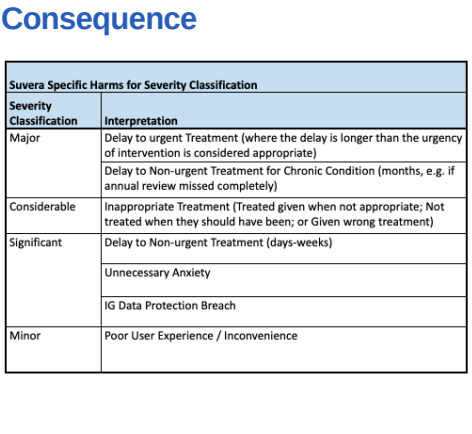
Risk Status

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

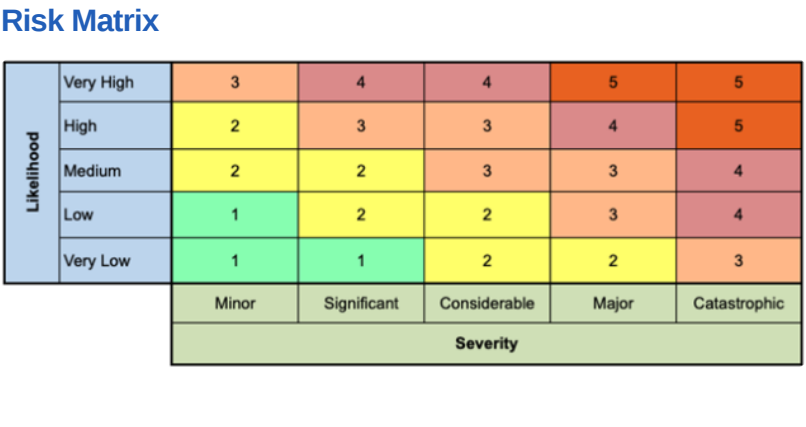
Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible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

Consequence



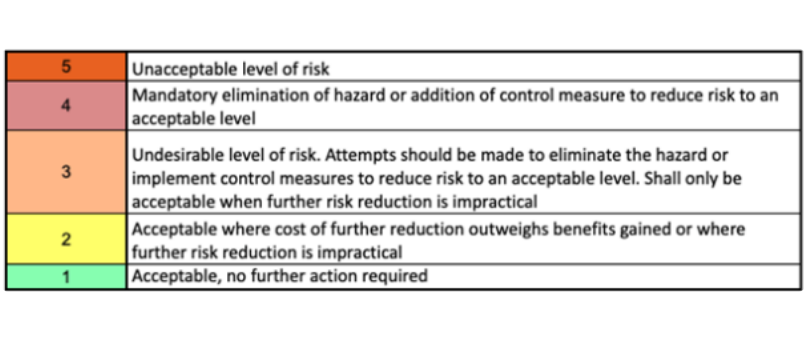
Suvera Specific Harms for Severity Classification	
Severity Classification	**Interpretation**
Major	Delay to urgent Treatment (where the delay is longer than the urgency of intervention is considered appropriate) Delay to Non-urgent Treatment for Chronic Condition (months, e.g. if annual review missed 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

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				

Risk Acceptability Criteria



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