DCB0129 Clinical Safety Case Report Suvera Planner

Suvera

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Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Ryan Peggs	Technical Director	11 August 2025	1.0
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Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Yasmin Karsan	Clinical Safety Officer	11 August 2025	1.0
Pratyusha Mohan	Clinical Safety Officer	9 February 2026	1.1

Related Documents

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

Doc Reference Number	Title	Version
1	Suvera Clinical Risk Management System	0.8
2	Product Clinical Safety Hazard Log - Suvera Planner	1.0
3	Functional and Non-Functional Testing Strategy	1.0
4	Incident Reporting Meeting Minutes	-
5	Incident Reporting Procedure	1.1
6	Governance Dashboard	-
7	Clinical Product Safety Platform Log	-
8	Hazard Identification Workshops	1.0
9	UCLP Risk Scoring	-
10	Product development lifecycle	-

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Abbreviations & Definitions

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

Introduction

The purpose of this 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 safe for its intended use as per the DCB0129 standard.

It demonstrates that:

- 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 Planner supports practice teams to deliver effective recall and ongoing management of specific long-term conditions (LTCs) in primary care, including associated high-risk drug monitoring where relevant.

The solution enables patients with eligible LTCs to be viewed holistically. It presents a complete picture of each patient's needs, allowing practices to recall patients for investigations and reviews more efficiently and consistently.

The service includes:

- Pre-go-live setup: An EHR data analyst from the Suvera team works closely with the practice to ensure EHR integration is correctly configured and that all relevant data is visible within the Planner.
- Ongoing support: Once live, practices receive continued technical support to ensure smooth and effective use of the system.
- Patient cohort identification: Practice users can identify and review cohorts of patients who require recall. Recalls are carried out using the Suvera Planner, with activity reflected through relevant coded entries in the patient record.

In Scope

The scope of this Clinical Product Clinical Safety Case Report, and the associated activities, is limited to the development and use of the Planner Digital Health Solution only.

Out of Scope

The following areas are explicitly excluded from this Clinical Safety Case Report:

- Clinical governance of practice clinicians conducting clinical reviews of patients following recall.
- Interactions with the GP Electronic Health Record (EHR), except where a direct error (for example, a transcription error) may occur between the GP EHR and the Suvera Planner Platform.
- Information governance and data privacy, except where these may have a direct impact on patient safety. Information governance is managed under a separate process.
- System-level views of third-party digital health solutions used by practice staff, including but not limited to:
  - Communication tools
  - Appointment scheduling systems
  - Video conferencing or telephone platforms
  - GP EHR systems

Aims (Intended Use)

Key clinical benefits

- Identification of patients with long-term conditions (see list below), including any high-risk medication monitoring required for those patients, and support for associated investigations, clinical review and patient recall for both groups.

Clinical Context

The Suvera planner is a read-only tool that supports practice teams in delivering the recall of patients with specific long term conditions and high risk medication monitoring within primary care. Recalls will appear within Suvera planner when coded in the EHR in line with national or local business rules.

The planner incorporates an algorithmic rules engine to determine which investigations a patient may require and the appropriate monitoring frequency. The rules are informed by recognised national clinical guidance and standards including:

- QOF
- CQC
- NICE
- SPS
- NHSE
- BNF
- BSG
- MHRA

The system analyses coded data within the patient record to identify when recommended investigations are due or approaching their due date. Recall prompts are generated according to predefined timing thresholds:

- 2 weeks before it's overdue if the investigation frequency is ≤3 months
- 1 month before it's overdue if the investigation frequency is >3 months

Current conditions supported are:

- Atrial Fibrillation = BMI every 12 months
- Asthma = ACT & Smoking Status every 12 months
- CHD = BMI, BP, HbA1c, Lipids, Renal Function & Smoking Status every 12 months
- CKD (All) = BMI & BP every 12 months
- CKD 1+ = Renal Function & uACR at varying frequencies depending on their last GFR and ACR results in accordance with NICE NG203 and NICE CKS****
- CKD 3+ = FBC every 12 months
- Coeliac = B12, Calcium, Coeliac Serology, FBC, Folate, LFT, Renal Function, TFT & Vitamin D every 12 months
- COCP = BMI & BP every 12 months
- COPD = Smoking Status every 12 months
- Diabetes (All) = BP, Smoking Status & uACR every 12 months
- Diabetes (Gestational) = HbA1c every 12 months
- Diabetes (T1) = HbA1c every 6 months
- Diabetes (T2) = HbA1c, Lipids & Renal Function every 12 months
- Down's Syndrome = TFT every 12 months
- Frailty = BMI every 12 months
- Heart Failure = BMI, BP & Renal Function every 6 months
- Hypertension = BMI, BP & Renal Function every 12 months
- Hyperthyroidism = TFT every 12 months
- Hypothyroidism = BMI & TFT every 12 months
- NDH = HbA1c every 12 months
- SMI (bipolar, psychotic disorders, schizophrenia) = BMI, BP, FBC, HbA1c, LFT, Lipids & Renal Function every 12 months
- Stroke / TIA = BMI, BP & Lipids every 12 monthsQOF

For the above cohort of patients, if they also need any medication monitoring the following are recommended on planner:

- ACE / ARB = Renal Function every 12 months
- ADHD meds (Methylphenidate, Lisdexamfetamine, Dexamfetamine, Atomexitine, Guanfacine) = BMI & BP every 6 months
- Aminosalicylates (5-ASA - Mesalazine, Olsalazine, Balsalazide, Sulfasalazine) = Renal Function every 12 months
- Amiodarone = LFT, Magnesium, Renal Function & TFT every 6 months
- Antipsychotics (1st Gen, Risperidone, Paliperidone, Amisulpride, Lurasidone) = Prolactin every 12 months
- Antipsychotics (All) = BMI, FBC, HbA1c, LFT, Lipids & Renal Function every 12 months
- Azathioprine = FBC, LFT & Renal Function every 3 months
- Azithromycin = LFT every 6 months
- Carbimazole = TFT every 3 months
- Ciclosporin = BP, HbA1c, LFT, FBC & Renal Function every 1 month
- Corticosteroids = HbA1c every 3 months
- Corticosteroids = BMI, Lipids & Renal Function every 12 months
- Denosumab = Calcium, Renal Function & Vitamin D every 6 months
- Digoxin = Calcium, Magnesium & Renal Function every 12 months
- Diuretics = Renal Function every 6 months
- DOAC = FBC, LFT & Renal Function at varying frequencies depending on CrCl & frailty*
- DOAC = BMI & BP every 12 months
- Dronedarone = LFT & Renal Function every 6 months
- Hydroxycarbamide = FBC, LFT, Renal Function & Urate every 3 months
- Leflunomide = BMI, BP, FBC, LFT & Renal Function every 3 months
- Levothyroxine = TFT every 12 months
- Lithium = Lithium Level at varying frequencies depending on patient age, drug interactions, elevated calcium, latest lithium concentration & pregnancy**
- Lithium = BMI, Calcium, Renal Function 7 TFT every 6 months
- Mercaptopurine = FBC, LFT & Renal Function every 3 months
- Metformin = Renal Function every 12 months
- Methotrexate = FBC, LFT & Renal Function every 3 months
- Minocycline (6th month onwards) = LFT every 3 months
- Mirabegron = BP every 12 months
- Mycophenolate = FBC, LFT & Renal Function every 3 months
- Penicillamine = FBC, LFT & Renal Function every 3 months
- Peripheral Arterial disease = BMI, BP & Lipids every 12 months
- Phenytoin = Calcium, FBC, LFT, Renal Function & Vitamin D every 5 years
- Propylthiouracil = TFT every 3 months
- Riluzole = FBC & LFT every 12 months
- Roflumilast = BMI every 12 months
- Sulfasalazine (1st year) = FBC, LFT & Renal Function every 3 months
- Sulfasalazine (2nd year onwards) = FBC, LFT & Renal Function every 12 months
- Tacrolimus = BP every 3 months
- Testosterone = FBC, Lipids, LFT & Testosterone Level every 12 months
- Testosterone (male >45 years old) = PSA every 12 months
- Theophylline = Theophylline Level every 12 months
- Valproate = BMI, FBC & LFT every 12 months
- Warfarin = INR at varying frequencies depending on the last INR result***

* DOAC variable frequencies

FBC, LFT & UE are due:

- Every 2 months when CrCl is 15-24
- Every 3 months when CrCl is 25-34
- Every 4 months when CrCl is 35-44 or frail or ≥ 75 years old
- Every 5 months when CrCl is 45-54 & not frail & not ≥ 75 years old
- Every 6 months when CrCl is 55-59 & not frail & not ≥ 75 years old
- Every 12 months when CrCl is 0-14 or 60+ & not frail & not ≥ 75 years old

** Lithium variable frequencies

If any of the following apply, Lithium Level is due every 3 months:

- Age 65+
- Pregnant
- Elevated calcium (> 2.6mmol/L)
- Latest lithium concentration ≥ 0.8 mmol/l
- Drugs (Diuretrics, NSAIDs, Haloperidol, Carbamazepine, Dapagliflozin, Antidepressants or ACE Inhibitors)

If none apply, Lithium Level is due every 6 months.

*** Warfarin variable frequencies

If the last INR result is ≥ 5, INR is due every 2 weeks. If the last INR result is < 5, INR is due every 3 months.

**** CKD 1+ variable frequencies

Planner follows the table of frequencies in NICE NG203, which depends on the last GFR and ACR results. If there is no eGFR or no uACR result on record, it is due immediately.

Users / Scale

- Staff (GPs, Clinical Pharmacists, Nurses, Administrators) at all/any of our partner GP practices

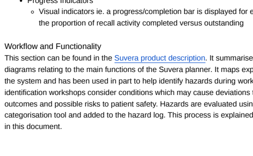
System Functionality Overview

Software Identification

Software Description

Planner allows partners to have visibility of national and local targets, and to efficiently manage recall to achieve those targets.

Deployment and Technical Architecture



Features

- View all patients at the practice who require recall for supported long-term conditions, as well as any high-risk medication monitoring required for those patients.
- Distinguish between:
  - Patients under Suvera care
  - Patients under practice care
- Search for individual patients using NHS number
- For each patient planner displays:
  - investigations required
  - reviews required
  - target areas.
- Patients are sorted by default according to furthest from completion.
  - Alternative sorting options include:
    - UCLP/CCLP risk score
    - Closest to completion
- Users are able to filter patient lists using multiple criteria, including:
  - Target area / condition
  - Month of birth
  - Care ownership (Suvera-led vs Practice-led)
- The interface provides dedicated tabs or views to support operational workflow, including:
  - All patients
  - Recall not started
  - Recall in process
  - Review (1+ area has been reviewed, or the review is booked)
  - Complete
- Recall actions can be Initiated:
  - Individually for a single patient
  - In bulk for multiple patients, either my multi-select or "select all" within a filtered list
- Progress Indicators
  - Visual indicators ie. a progress/completion bar is displayed for each patient to show the proportion of recall activity completed versus outstanding

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 planner. 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

Planner users include staff (GPs, Clinical Pharmacists, Nurses, Administrators) at each partner GP practice.

System dependencies

Integrations

- EMIS Partner API (EMIS partners only) - the latest patient medical records are fetched using the EMIS Partner API. When a medical record is updated, the patient's national and local targets are re-calculated. These target statuses and portions of the patient's medical record are stored in MongoDB so users are able to track target progress and to know what reviews and investigations are remaining for each patient.

IM1 Connection

This encompasses two integrations:

- Bulk which is the ability to read information from the EHR (EMIS and TPP), which happens daily
- Transaction which is the ability to write back into the EHR one patient at a time in real time

This may be contracted and assured under either national IM1 terms, or directly with EMIS, as commercially appropriate

Third-party dependencies

- MongoDB Atlas - used to store patient lists, national and local target statuses, and data points from the medical record. Using the eu-west-2 (London) region.
- AWS - cloud based infrastructure including the CDN for frontend and API and compute for backend.
- Pathology requesting platform (ICE/tQuest)
- Twilio, which is used to send SMS notifications to patients
- Hero Health, which is used to send patient-facing booking links to arrange blood test and review appointments.

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.

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 Pratyusha Mohan	*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 appendix A.

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, 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 established by the safety processes defined in DCB0129. 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	3	0	0	0
Monitored	0	0	0	0	0
Transferred	0	0	0	0	0
Subtotal	0	3	0	0	0
Total			3		

Risk Review

Three hazards have been identified and accepted. Three hazards have the status "acceptable where cost of reduction outweighs benefits", these risks are sufficiently accepted and are continuously monitored. These risks include examples such as erroneous/missing data. Controls for this type of risk are associated with software design and functionality. This includes custom built tests, audits and self reported discrepancies of functionality via a monitored technology support channel. Further details of these hazards and their controls can be found in the hazard log.

Hazards are continuously monitored and reviewed during audits.

Hazard Log

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 work as expected and result in Correct data being shown for the inputs provided)
- Safety testing (part of functionality testing, but check clinical parameters at all thresholds and boundaries - eg, UCLP risk classification etc)
- Sequence testing (larger e2e tests that simulate user behaviours over multiple day flows)

We currently have these tests:
4224 tests for the backend
670 tests for the partner dashboard UX

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

We 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 Planner supports practice teams to deliver effective recall and ongoing management of specific long-term conditions (LTCs) in primary care, including associated high-risk drug monitoring where relevant.

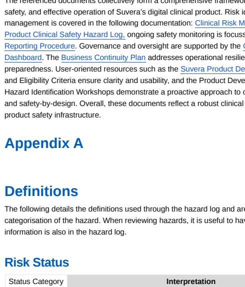
The solution enables patients with eligible LTCs to be viewed holistically. It presents a complete picture of each patient's needs, allowing practices to recall patients for investigations and reviews more efficiently and consistently.

The intended use of the Suvera planner 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 undergone witness testing with system supplier(s), with issues identified during this testing series resolved prior to launch. Future iterations are subject to internal and external validation via the RFC process, as required under the terms of those agreements. Identified hazards and associated mitigations continue to be monitored and reviewed as part of ongoing clinical safety governance.

In light of the above, I am satisfied that the Suvera planner has had appropriate 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 at routine intervals.

Dr Pratyusha Mohan | Clinical Safety Officer | GMC: 7134032



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 majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will
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
	High	2	3	3
	Medium	2	2	3
	Low	1	2	2
	Very Low	1	1	2
		Minor	Significant	Considerable
		Severity		

Risk Acceptability Criteria

5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of co acceptable level
3	Undesirable level of risk. Attempts should be made implement control measures to reduce risk to an a acceptable when further risk reduction is impracti
2	Acceptable where cost of further reduction outwe further risk reduction is impractical
1	Acceptable, no further action required