DCB0129 Clinical Safety Case Report Suvera Recall

The Clinical Safety Case Report (CSCR) summarises and reviews the clinical safety activities performed to support the implementation, deployment and use of product(s), relative to their phase of the product lifecycle.

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Document Management

Revision History

Version	Date	Summary of changes	Author
6.0	Oct 26, 2026, 18:55	Updated recall architecture diagrams (changed AI workflows to multi-step workflows)	Pratyusha Mohan
5.0	Sep 23, 2026, 15:49	Updated deployment architecture diagram.	Pratyusha Mohan
4.0	Sep 23, 2026, 12:58	Added the Clinical Safety Case Report overview, document management details, and confidentiality notice.	Pratyusha Mohan
3.0	Sep 23, 2026, 12:53	Updated hazard assessment details to reflect that all active hazards now sit within acceptable residual risk bands.	Pratyusha Mohan
2.0	Sep 18, 2026, 15:06	Updated hazard assessment details to reflect the scope of Recall.	Pratyusha Mohan
1.4	Jun 08, 2026, 11:40	Updated risk summary	Pratyusha Mohan
1.3	May 08, 2026, 12:08	Updated to remove hazards related to virtual clinic	Pratyusha Mohan
1.2	Apr 23, 2026, 15:42	Updated after medication monitoring release on planner	Pratyusha Mohan
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1.0	Aug 11, 2025, 00:00	Uplifted and Baselined	Ryan Peggs

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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

Suvera Recall is a cloud-based clinical tool developed by Suvera to support GP practice teams in delivering effective recall and ongoing management of patients with long-term conditions (LTCs) and patients requiring medication monitoring in primary care. Recall integrates with existing GP clinical systems (EMIS and TPP SystmOne) and uses an algorithmic rules engine, informed by recognised national clinical guidance and standards, to identify when recommended investigations or reviews are due for individual patients.

Recall enables practice teams to view patient cohorts holistically, presenting a complete picture of each patient's outstanding investigations, reviews, and target areas. This supports more consistent, efficient, and complete recall processes and reduces the risk of patients being lost to follow-up. Practice staff can initiate recall actions within Recall; corresponding activity is documented back into the patient's electronic health record via coded entries.

The service encompasses three components: pre-go-live setup, in which a Suvera EHR data analyst works with the practice to ensure the integration is correctly configured and all relevant data is visible within Recall; ongoing technical support to ensure effective use of the system once live; and patient cohort identification and recall, enabling practice users to review and act on patients requiring recall.

Recall does not replace clinical judgement or existing clinical workflows. It supplements them by surfacing information from the patient's existing EHR record and supporting the recall process. Clinical decisions remain the responsibility of the practice clinician.

In relation to clinical safety, this plan covers all clinical functions of Recall with the potential to impact patient safety. Primary clinical safety considerations relate to the accuracy, completeness, and availability of data presented to users — specifically, the risk that missing, incorrect, or inaccessible data could lead to delayed, unnecessary, or inappropriate clinical action. As Recall also writes recall activity back to the EHR, the accuracy and integrity of data recorded in the patient record is within scope.

The current phase of the programme is the deployment phase. Any future phases involving new clinical conditions, medication monitoring rules, or significant changes to existing functionality will be addressed through a revised Clinical Risk Management Plan.

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 Recall 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 Recall.
- 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) and patients requiring medication monitoring, and support for associated investigations, clinical review, and patient recall for both groups.

Clinical Context

Recall is a 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 Recall when coded in the EHR in line with national or local business rules.

Recall 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
- 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. The logic used is listed here. Any changes to clinical logic or rules are subject to the product development lifecycle, with appropriate clinical team review and input throughout.

Users / Scale

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

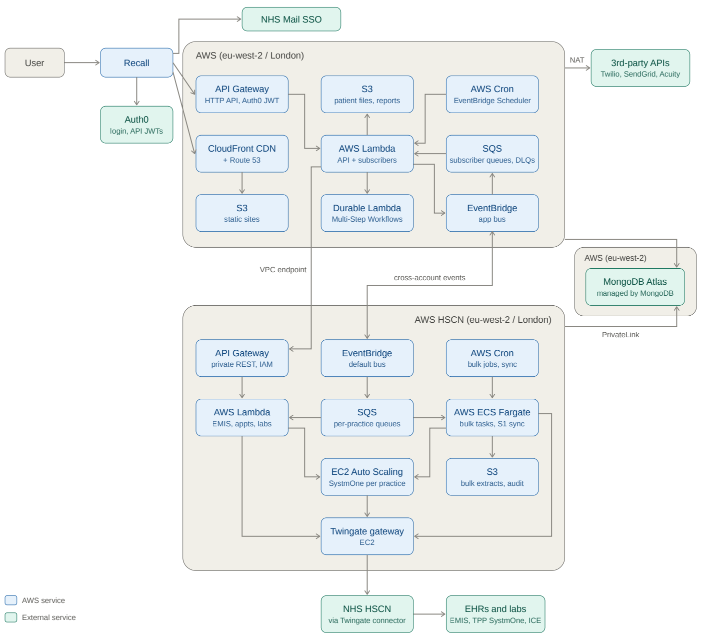
System Functionality Overview

Software Identification

Software Description

Recall 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 Recall 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 by 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

Scope / project boundaries

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

System dependencies

Integrations

- Read
  - Bulk (EMIS only): changes to patient medical records are sent from the EHR to Suvera daily
  - Transaction (EMIS + TPP): read full patient records, one patient at a time, in real time
- Write
  - Transaction (EMIS + TPP): write back into the EHR, one patient at a time, in real time

The above integrations are contracted and assured under either national IM1 terms, or directly with EMIS or TPP, as commercially appropriate.

Third-party dependencies

Information risks with third parties are covered in our DPIA and DPA. Third party providers embedded within the platform are considered part of the platform product for clinical risk assessment.

- Acuity - appointment scheduling system, non-integrated with the EHR
- AWS - cloud based infrastructure including the CDN for frontend and API and compute for backend.
- MongoDB Atlas - used to store all medical record data. Hosted on our behalf in the AWS eu-west-2 (London) region.
- Pathology requesting platform (ICE/tQuest)
- Twilio - SMS messaging system
- Hero Health - used to generate patient-facing appointment booking links integrated with the EHR

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	12	13
Significant	1	-
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	12	13
Significant	1	-
High	-	-
Very High	-	-

Risk Review

Of the 15 active hazards scoped to Recall, all now sit within acceptable residual risk bands (2 Low – Acceptable, 13 Moderate – Acceptable where the cost of further reduction outweighs the benefit). One hazard, **HAZ-017** (patient recalled or has investigations requested inappropriately), carried an initial risk of Significant/Undesirable, driven by the risk of investigation request volume overwhelming the receiving lab; this has been reduced to Moderate residual risk through a floor on proactive investigation intervals, a two-step select-review-send process for bulk recall, and request spacing/timeout controls, supported by an operational track record showing no incidents of lab overload since Recall went live.
Controls for the remaining hazards are integrated into software design and functionality, comprising custom-built tests, audits and self-reported discrepancies via a monitored technology support channel. Further detail on all 15 hazards is available in the hazard log. Hazards are continuously monitored and reviewed during audits.

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 is because Recall does not perform a primary medical purpose. While Recall supports monitoring of long-term conditions and medication, this is achieved through algorithmic, logic-based coding that identifies when a recommended investigation, review, or monitoring check is due, and presents this information for practice staff to review and act on. Recall does not itself interpret clinical results, generate clinical recommendations, or perform any of the diagnostic or therapeutic functions that meet the MHRA's definitions — the diagnosis, treatment, and clinical decision-making remain with the practice.

This position will be reviewed periodically.

Summary Safety Statement

Recall supports GP practice teams in delivering effective recall and ongoing management of patients with long-term conditions (LTCs) and patients requiring medication monitoring in primary care. The solution enables patients to be viewed holistically, presenting a complete picture of each patient's needs and allowing practices to recall patients for investigations and reviews more consistently and efficiently.

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

Recall 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 change control 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.

Residual risks have been assessed and are considered acceptable in the context of the clinical benefits provided.

In light of the above, I am satisfied that Recall has had appropriate clinical risk management activities undertaken. The artefacts 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

I. Habli et al. *Safety Science 110 (2018) 324–335*

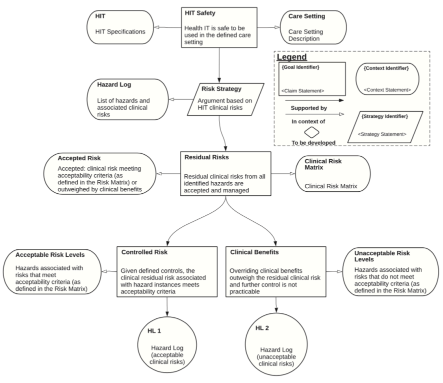

HIT
HIT Specifications
HIT Safety
Health IT is safe to be used in the defined care setting
Care Setting
Care Setting Description
Legend
{Goal Identifier}
<Claim Statement>
{Context Identifier}
<Context Statement>
Supported by
In context of
To be developed
{Strategy Identifier}
<Strategy Statement>
Hazard Log
List of hazards and associated clinical risks
Risk Strategy
Argument based on HIT clinical risks
Accepted Risk
Accepted: clinical risk meeting acceptability criteria (as defined in the Risk Matrix) or outweighed by clinical benefits
Residual Risks
Residual clinical risks from all identified hazards are accepted and managed
Clinical Risk Matrix
Clinical Risk Matrix
Acceptable Risk Levels
Hazards associated with risks that meet acceptability criteria (as defined in the Risk Matrix)
Controlled Risk
Given defined controls, the clinical residual risk associated with hazard instances meets acceptability criteria
Clinical Benefits
Overriding clinical benefits outweigh the residual clinical risk and further control is not practicable
Unacceptable Risk Levels
Hazards associated with risks that do not meet acceptability criteria (as defined in the Risk Matrix)
HL 1
Hazard Log (acceptable clinical risks)
HL 2
Hazard Log (unacceptable clinical risks)

Fig. 2. Risk-based argument structure.

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

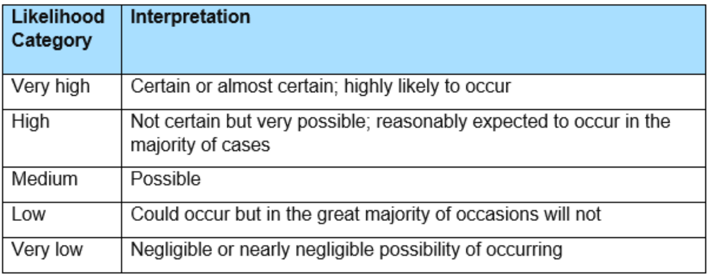
Definitions

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

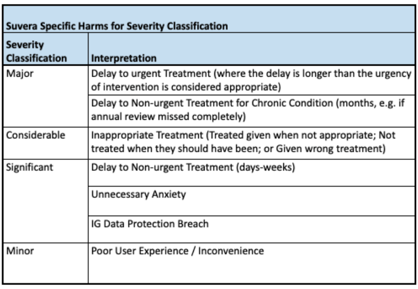
Status Category	Interpretation
	Status
Accepted	Clinical risk meets acceptability criteria (as defined in risk matrix) or is outweighed by clinical benefits. Risk is 'as low as reasonably possible (ALARP)'
Monitored	Clinical Risk continues to be monitored, with additional controls yet to be introduced 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

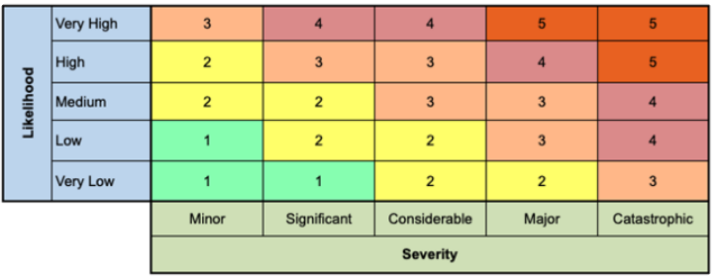
Consequence



Suvera Specific Harms for Severity Classification

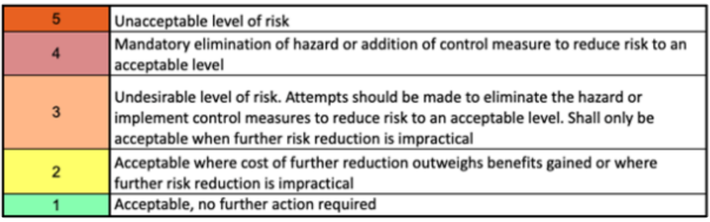
Severity Classification	Interpretation
Major	Delay to urgent Treatment (where the delay is longer than the urgency of intervention is considered appropriate)
	Delay to Non-urgent Treatment for Chronic Condition (months, e.g. if annual review missed completely)
Considerable	Inappropriate Treatment (Treated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