Template guidance

This is a draft CSCR prepared by Suvera in accordance with DCB0160 to support partner practices deploying Recall. It is intended as a starting point for the deploying healthcare organisation's own clinical safety documentation. The deploying organisation's CSO should review, amend as necessary to reflect their local deployment context, and formally approve this document before Recall is deployed.
Sections requiring organisation-specific input are indicated throughout.
We suggest you keep the language at a high enough level such that it stays representative for at least a year.
Ensure all relevant stakeholders have reviewed the document, and that reviews and approvals are recorded under Document Management.
Text in grey italics gives examples for you to follow, and should be deleted or replaced with the appropriate information.
Text highlighted in yellow requires attention
Delete this information callout once you have reviewed the document

Clinical Safety Case Report

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

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Introduction

The Clinical Safety Case Report (CSCR) summarises and reviews the clinical safety activities carried out to support the implementation, deployment and use of Recall, relative to the phase of the product lifecycle. The CSCR is structured to be iterative as new functionality and changes are introduced.
The CSCR forms part of our Clinical Risk Management File and is part of a set of clinical safety documentation, which has been produced in order to meet requirements of the DCB0160 clinical risk management standard. This report contains the software definition, clinical hazards and mitigation/acceptance, and supporting evidence to provide an assurance statement on the clinical safety of the product.

Purpose

The purpose of this document is to outline the health IT product being deployed, including its intended use and scope of deployment. It will also outline the relevant Clinical Risk Management processes utilised, and summarise clinical risk analysis, with a focus on identifying, estimating and mitigating clinical safety hazards that may arise from the deployment and use of the product.
Specifically, this current CSCR has been written to support the implementation of Recall as of [Insert date]. Subsequent and wider deployment of existing or new products will be supported by appropriate Clinical Risk Management (CRM) and an uplift to this CSCR.

Scope

This CSCR applies to Recall, which is to be deployed at [Healthcare organisation sites]. This document also applies to any local customisations or specific configurations made to Recall for the purposes of this specific deployment.
This scope extends to all clinical risk management linked activities undertaken during Recall's life cycle. All clinical functions and use cases that have potential to cause harm to patients and/or system users are incorporated.

Medical Device Regulatory Assessment

Recall does not meet criteria to be classified as a Medical Device, and therefore does not fall within the UK Medical Devices Regulations, and has not been formally assessed by the Medicines and Healthcare products Regulatory Agency (MHRA). 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.

Service Overview

Manufacturer background

Suvera is a digital health technology company that develops and maintains Recall software for NHS primary care. Recall looks across a practice's patient population, identifies gaps in required care such as overdue investigations, reviews, or medication monitoring, and enables practices to bring those patients in for recall. Recall integrates with existing GP clinical systems, including EMIS and TPP SystmOne, so that patient data flows into the platform without duplicate record-keeping, and recall and monitoring activity is coded back into the patient's electronic health record.

Clinical context

Give a brief overview of clinical practice prior to the introduction of the new digital health technology.
Give a brief overview of how clinical practice and workflows or pathways will change as a result of introduction of the new digital health technology, and the clinical context in which it will be used.

Development lifecycle

The current phase of the product life cycle is the deployment phase.

Existing systems

Describe any existing IT systems the product replaces or interfaces with

Intended use

- Intended purpose:

Recall 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:

1. 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 Recall.
2. 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 Recall platform, with activity reflected through relevant coded entries in the patient record.

- Intended users (primary, secondary, tertiary):
  - Staff at the GP practice (GPs, Clinical Pharmacists, Nurses, Administrators)
  - Describe who will manage the system (e.g. clinical or administrative staff in GP practices)
- Use environment:
  - Recall is a cloud based web app that is used by healthcare practitioners in their browser on GP practice computers
- Operating principle:
  - Recall analyses coded data in the patient's electronic health record against national and local clinical guidance to identify when a recommended investigation, review, or medication monitoring check is due or approaching. Patients meeting these criteria appear in Recall's dashboard, where practice staff can review the outstanding items, initiate recall actions individually or in bulk, and track progress through to completion. Once an action is carried out, the corresponding activity is coded back into the patient's electronic health record, keeping Recall's view of each patient current.

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 Logic:
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:

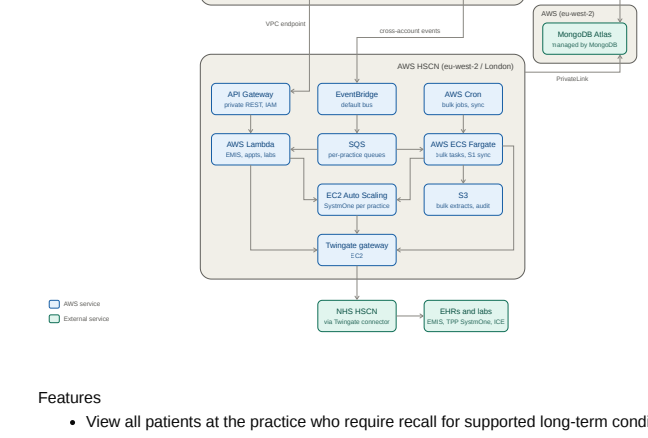
- QOF
- NICE
- SPS
- NHSE
- BNF
- BSG
- MHRA

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.

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 of deployment
Describe the scope of deployment that this report refers to. It could be the number of healthcare organisation sites and/or the number of patients affected.

Clinical Risk Management System

We have established a Clinical Risk Management System, with processes in place for both proactive and reactive clinical risk control to ensure that any credible hazards and associated risks can be identified and anticipated as possible before they occur and any subsequent incidents that occur can be detected and resolved effectively.
Suvera, as manufacturer, maintains a Clinical Safety Change Management Procedure covering software releases, ensuring changes are assessed for potential clinical risk before release, in line with our Clinical Risk Management Plan. As the deploying organisation, we review Suvera's release notes and changes to assess whether they affect our local risk position, and update our own hazard log and clinical safety documentation accordingly.

Our CRM activities cover the following:

- Risk Analysis
- Scope Definition
- Clinical Hazard Identification
- Clinical Risk Estimation
- Risk Evaluation
- Evaluation of initial level of risk of each identified hazard using pre-defined criteria
- Risk Control
- Control Option Analysis
- Clinical Risk Benefit Analysis
- Control Measure Implementation
- Completeness Evaluation

This comprehensive and repeatable clinical risk management process is applied throughout the lifecycle of the product.

Key personnel

The list below identifies people key responsible for clinical safety within our organisation, making up the Clinical Safety team.

Clinical Safety team

Name	Role	Responsibilities
Example 1	*Practice Clinical Safety Officer*	*Oversee all clinical risk management processes in the practice; Maintain the clinical risk management documentation; Approve clinical risk management documentation; Lead hazard identification reviews; Escalate clinical risk management issues; Ensure deployment of the Health IT System in the practice*
Example 2	*Practice Manager*	*Communicate user feedback with CSO; Attend hazard identification reviews; Support / escalate clinical risk management issues*

Clinical Safety Officer

Name	Professional qualifications	Professional Body	Competency/Skills/Experience	Clinical Safety Training
[Insert]	[Insert]	[Insert]	[Insert]	[Insert]

All documents created as part of the Clinical Safety Management System are maintained, version controlled and managed by the Clinical Safety Team and authorised by the Clinical Safety Officer. Documents are stored in the Clinical Risk Management File, which has the appropriate access control measures in place.

Clinical safety review process

Clinical Safety change management procedure
Suvera, as manufacturer, is responsible for **Clinical Safety Change Management Procedure**. This ensures any product modifications or updates, or any bugs that have been logged, are assessed for potential clinical risk prior to release into a live environment, and reviewed by Suvera's Clinical Safety Officer. Suvera's hazard log is updated accordingly. As the deploying organisation, we review any change notifications from Suvera and update our own hazard log and clinical safety documentation where changes affect our local risk position.
Clinical Safety Incident management procedure
Suvera, as manufacturer, maintains a **Clinical Safety Incident Management Procedure**, in which incidents that might impact patient safety are reported to and managed by Suvera, with a requirement for their CSO's assessment of clinical risk. As the deploying organisation, we report any safety incidents we identify to Suvera in line with this procedure, and separately manage incidents arising from our own local configuration, use, or procedures through our own incident management arrangements.

Clinical Risk Analysis

As is the nature of clinical software, hazards are always likely to be present. It is important to reduce the likelihood of these hazards occurring, as well as the potential impact of each hazard.
Clinical Risk Analysis includes identifying all hazards, description of patient safety consequences, explanation of hazard causes and effects, and identification of existing mitigating controls and the evaluation of clinical risk.
Hazard Identification (HAZID) is performed using the Structured What If Technique (SWIFT) and/or Functional Failure Analysis (FFA). At each step of the process; a checklist of possible 'things that could go wrong' are discovered by following structured discussions, prompted by a range of 'What if' questions covering human, technical and organisational factors within processes and procedures that may affect safety and the performance of the Health IT System in terms of what could happen, what a user could do and what the system does. This hazard assessment considers information security, operational security, information governance, privacy and confidentiality and human behaviour and usability / GUI hazards and threats that could potentially have an impact on patient safety.
Hazards are defined using the cause > effect > hazard > harm framework:

- Cause: Consider events or actions that occur in the care-pathway that causes a deviation in the intended care process. Have all the potential scenarios that could cause a hazard or threat to occur been considered?
- Effect: The deviation that occurs in the care-pathway as a result of the cause
- Hazard: The condition that is created in the care-pathway as a result of the effect that has the potential to cause harm
- Harm: The realisation of harm to the patient

Details of any completed hazard assessment workshops can be found in the Hazard Workshop section.

Description of patient safety consequences

What are the patient safety consequences of the product? It can be helpful to divide this into direct and indirect consequences (Example indirect consequences may be delay to patient care, delay in receiving clinical/administrative support, wasted clinical resources)

Recall is a tool that assists practices to recall patients for their long term conditions. As with any clinical software, there are potential indirect safety consequences that could arise from its use. These are primarily related to the accuracy, completeness and availability of the data presented to users. Potential patient safety consequences include:

- **Delay to care** — If Recall fails to identify a patient requiring recall, or presents incomplete data, necessary investigations or reviews may be delayed.
- **Unnecessary or repeated investigations** — If data is missing or not correctly reflected from the EHR, a patient may be recalled for investigations that have already been completed.
- **Inappropriate clinical action** — If incorrect or outdated data is presented on the dashboard, a clinician may make decisions based on inaccurate information.
- **Wasted clinical resources** — Inaccurate or incomplete recall lists may lead to unnecessary clinical activity or administrative effort.
- **Patient anxiety or inconvenience** — Patients may be contacted for recall unnecessarily, or experience delays in being contacted when a review is due.

Clinical Risk Evaluation & Control

Each identified hazard is evaluated for the initial level of risk using pre-defined criteria.

The risk matrix grade is based on:

- Likelihood: How likely each identified consequence is to actually occur
- Consequence: For each combination of cause and hazard, were the hazard to be realised, what potential outcomes for patient safety are there
- Severity: The seriousness of each consequence is considered, in terms of individual patient harm

For each risk we consider the following as part of our evaluation:

- Actions: Actions taken or proposed to prevent or reduce the safety risk where possible.
- Acceptability: What top management consider to be acceptable risks and why
- Review: How often each residual risk/hazard is reassessed and actions evaluated

Qualitative probability

The defined levels for the probability of harm are as follows:

Likelihood Classification	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

Qualitative severity

The defined levels for the severity of harm are as follows:

Severity 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

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				

Risk Matrix key - Acceptability

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

The subsequent approach for review and re-evaluation of these hazards will be the responsibility of the clinical safety team which will include:

- Consider the existing safeguards which would prevent or reduce the safety risk.
- Given those safeguards, grade each risk using the combination of consequence severity and likelihood.
- Identify recommendations for mitigation or controlling hazards to reduce risk.
- Given those mitigations, re-grade each risk using the risk matrix.

Identified hazards

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	-	-

List of identified hazards

Hazard ID	Hazard	Initial Risk	Residual Risk
HAZ-001	Patient or clinical data missing or never captured	2	2
HAZ-002	Incorrect or outdated data presented on the dashboard	2	2
HAZ-003	Patient or clinical data temporarily inaccessible	2	2
HAZ-005	Patient receives 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 is missed	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 receives inadequate care due to calculations within the dashboard	2	2
HAZ-017	Patient recalled or has investigations requested inappropriately	3	2
HAZ-019	Unauthorised access to, or breach of, stored patient data	2	2
HAZ-020	Incorrect or miscoded clinical data written back to the EHR	2	2
HAZ-025	Patient faces their information being accidentally added to another patient's record	2	2
HAZ-028	Patient does not complete an action requested of them	2	2

Risk-benefit analysis and justification (if applicable)

No risk-benefit analysis is required. One hazard, HAZ-017, carries an initial risk score of 3 (Significant/Undesirable); as documented in the hazard log, controls have reduced this to a residual risk score of 2 (Moderate/Acceptable where the cost of further reduction outweighs the benefit), with no further risk-benefit justification currently required.

Discussion of relevant hazards

One hazard, **HAZ-017** (patient recalled or has investigations requested inappropriately), carried an initial risk score of 3 (Significant/Undesirable), driven by the risk of investigation request volume overwhelming the receiving lab. Controls - a floor on proactive investigation intervals, a two-step select-review-send process for bulk recall, and request spacing/timeout controls - have reduced this to a residual risk score of 2 (Moderate). No incidents of lab system overload have occurred since Recall went live, and responsibility for managing request volume is shared with the receiving lab's own system.
All hazards, including HAZ-017, now carry a residual risk score of 1 or 2 (Acceptable or Acceptable where the cost of further reduction outweighs the benefit), with controls integrated into software design and functionality. Full detail on all hazards, causes, and controls is maintained in the hazard log.

Transferred hazards and controls

None of the hazards currently scoped to Recall have controls transferred to the deploying organisation; all are fully controlled by Suvera as manufacturer. This position should be re-checked against the hazard log periodically, as it may change as new hazards are identified.

Hazard log

The full **Hazard Log** can be found separately. It is provided in the NHS Digital format, and provides evidence to support compliance with DCB0160

Hazard Workshops

Include details of completed hazard workshops here (such as dates and attendees)

Test issues

Summary of any outstanding test issues or defects within the system and the impact on clinical safety

Assessment of third party products

Include a list of any third party products and consider their use and potential clinical safety impact

Third party product	Clinical safety consideration
Name of third party product	*Consider potential impact on clinical safety if any*

Summary Safety Statement

Recall 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, presenting a complete picture of each patient's needs and allowing the deploying healthcare organisation to recall patients for investigations and reviews more efficiently and consistently.
As the Clinical Safety Officer of the deploying organisation, I have reviewed the manufacturer's (Suvera's) clinical safety documentation, including the hazard log and the intended use of Recall. Fifteen hazards have been identified, all of which sit at an acceptable level of residual risk (Acceptable or Acceptable where the cost of further reduction outweighs the benefit), as set out in the Discussion of relevant hazards above.
In light of the above, I am satisfied that Recall has had appropriate clinical risk management activities undertaken and that the residual risk associated with its deployment at [healthcare organisation name/sites] is acceptable. 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.
For CSO review and sign-off - please confirm you are satisfied with this statement before approval. The summary safety statement to be written by the named CSO after analysis of identified hazards and risks. This must include the safety position of the Health IT System in the context of the intended deployment.

Quality Assurance and Document Approval

This CSCR has been developed, reviewed, and approved in accordance with the arrangement described within the **Clinical Risk Management Plan**.

References

Reference 1

DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems, NHS Digital, NHS England

Reference 2

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

Reference 3

Guidance: Medical device stand-alone software including apps (including IVDMDs), MHRA (Medicines & Healthcare products Regulatory Agency)