

# Clinical Risk Management System

## Musical Health Technologies (SingFit)

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# Document Management

## Version History

Version	Date	Summary of Changes
.1	10/06/2023	Initial Draft
1.0	11/8/2023	Initial Release
2.0	03/22/2024	Major Revision - detailed information added in the Clinical Risk Management (CRM) Governance Arrangements section (org chart, role descriptions, usability and human factors), clarity language added to the training and audits subsections

## Related Documents

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

Ref	Doc Reference Label	Title	Version
	CRMP	<a href="#">Clinical Risk Management Plan</a>	1.0
	CSCR	<a href="#">Clinical Safety Case Report</a>	2.0
	HL	<a href="#">Hazard Log</a>	2.0

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## Introduction

This Clinical Risk Management System (CRMS) outlines the processes to be followed to ensure that all healthcare IT used to support care within SingFit is developed, implemented and used in a safe manner.

This CRMS provides a framework that promotes the effective risk management, by SingFit, of potential health IT hazards and operational incidents.

This CRMS compliments existing risk management processes defined in SingFit's Clinical Risk Management Plan [\[CRMP\]](#) and wherever practical, uses existing procedures, processes and governance arrangements.

This CRMS addresses the requirements of DCB0129 [\[Ref\]](#) and DCB0160 [\[Ref\]](#) and follows best practice as promoted by NHS Digital.

## Purpose

The aim of the CRMS is to ensure that all of the SingFit staff involved with the development, implementation and use of healthcare IT systems are aware of the activities that are required to be undertaken to ensure patient safety is improved rather than compromised from the introduction of healthcare IT systems.

This Clinical Risk Management System will be reviewed periodically to ensure that:

- changes in working practices are incorporated
- issues identified through an established internal audit program are addressed
- the safety approach continues to adhere to the requirements of applicable international standards
- the system continues to protect the safety of patients in a complex and changing environment

## Audience

This document is for SingFit staff that are involved in ensuring the safety of healthcare IT systems, products or services.

## Scope

This applies to SingFit and to all subsequent updates or upgrades to systems. The minimum operating system required is 9.0 for Android devices and 14.0 for iOS devices. The policy also applies to any local customizations or specific configurations made to a healthcare IT system by SingFit.

If clarification is required of whether any system falls within scope of this CRMS this should be raised with the nominated Clinical Safety Officer (CSO). This nominated person provides clinical and organizational leadership on healthcare IT Patient Safety on behalf of the Organization.

## Definitions

Note - Also see the SingFit's Clinical Risk Management Plan [\[CRMP\]](#)

**CSO:** Clinical Safety Officer - the person responsible for ensuring that the digital therapeutic music platform Clinical Risk Management System is applied to all clinical systems. The Clinical Safety Officer (CSO) for the Organization is responsible for ensuring the safety of a healthcare IT system through the application of clinical risk management. The Clinical Safety Officer must hold a current registration with an appropriate professional body relevant to their training and experience. They also need to be suitably trained and qualified in risk management or have an understanding in principles of risk and safety as applied to healthcare IT systems. The Clinical Safety Officer ensures that the processes defined by the clinical risk management system are followed.

## Clinical Risk Management (CRM) Governance Arrangements

The responsibility for the digital therapeutic music platform within SingFit resides with the Compliance Team. Faults or incidents related to clinical safety and risks are reported in writing to the CSO (e.g., email). The Compliance Team, led by the CSO, conducts a thorough assessment of the reported faults to determine their impact on patient safety and collaborates with the Product and Technology Team to understand the technical aspects of the faults.

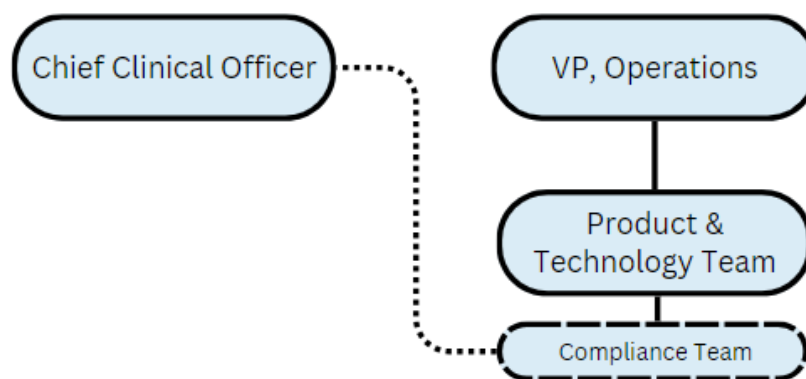
The personnel/teams involved in clinical risk management (see below) conducts a risk analysis to evaluate the severity and likelihood of harm associated with the reported faults. This analysis informs prioritization and decision-making regarding mitigation strategies. The strategies are then implemented to address the reported faults.

The Compliance Team and Product and Technology Team monitor the effectiveness of the implemented mitigation strategies and conduct follow-up assessments to ensure sustained improvement in clinical safety and risk management. The processes are documented and reviewed to determine if any additional measures are needed to prevent similar faults.

## Clinical Risk Management Team Organization

The Compliance Team is a subgroup of the Product & Technology Team. The Compliance Team is composed of the CSO and Data Protection Officer (DPO) and reports to both the Chief Clinical Officer and the VP, Operations.

The visual below provides an overview of the teams involved in clinical risk management .



## Personnel & Governance

The role and responsibilities for the clinical safety related positions are outlined below:

**Chief Clinical Officer (CCO)** - The CCO oversees the clinical safety and risk management within SingFit. This includes guidance on policies and procedures for patient safety, ensuring the app is up to date with best clinical practices, and assisting in the identification and mitigation of potential risks. The current CCO is a board-certified music therapist with over 15 years of experience and is also the co-founder of SingFit.

**VP Operations** - The VP of Operations oversees the operational aspects of the clinical safety and risk management within SingFit. This includes ensuring operational goals align with clinical safety objectives, providing input regarding comprehensive risk management strategies, and collaborating with the Compliance Team to implement and regularly assess organizational compliance such as incident reporting and analysis. The current VP of Operations has over 15 years of experience including leading digital health organizations.

**Product & Technology Team (PTT)** - The PTT is responsible for integrating clinical safety considerations into the product development processes including conducting risk assessments for new features or updates as well as ensuring that product releases comply with relevant regulatory requirements. The current PTT is composed of a board certified music therapist and a speech-language pathologist / neuropsychologist with over a decade of experience.

**Compliance Team (CT)** - The CT is responsible for ensuring adherence to regulatory standards and safeguarding patient information in clinical safety and risk management. The CT assesses and mitigates risks related to clinical practices and patient data security, implements policies and procedures to maintain compliance with relevant laws and regulations, and provides training to promote awareness and adherence to best clinical practices and data protection. At this time, the roles and responsibilities of CSO and DPO are assumed by the Senior Product Manager, a speech-language pathologist and neuropsychologist with 15 years of experience. They are HIPAA-certified and have completed the required NHS Digital foundation training course.

Additional responsibilities of the CSO were outlined in the 'Definitions' section of this document.

**User Representatives** - Additional ad hoc guidance and input regarding clinical safety is provided by selected user representatives from SingFit's routine user testing efforts. User testing is conducted throughout the year and is designed to assess the clinical utility of SingFit including usability. Users are selected based on their availability and interest.

## Clinical Risk Management Deliverables

### Clinical Risk Management File

SingFit will establish a Clinical Risk Management File (CRMF) for the digital therapeutic music platform. The purpose of the CRMF is to provide a central repository where all safety related information pertaining to SingFit is stored and controlled.

### Clinical Risk Management Plan

SingFit will establish a Clinical Risk Management Plan (CRMP) for the digital therapeutic music platform. The purpose of the CRMP is to identify the clinical risk management activities that are to be undertaken and the phasing of these activities in the project lifecycle. The CRMP will also identify the resources required to discharge these clinical risk management activities.

### Hazard Log

SingFit will establish and maintain a Hazard Log (HL) for the digital therapeutic music platform. The HL will be made available within the CRMF. The purpose of the HL is to manage the effective resolution and communication of hazard risk within The Organization.

### Clinical Safety Case

SingFit will establish and develop a Clinical Safety Case (CSC) for each safety related HIT system.

### Clinical Safety Case Report

SingFit will issue a Clinical Safety Case Report (CSCR) for each safety related healthcare IT system. The CSCR will be issued to support initial deployment and will be updated during the lifecycle of SingFit should the safety characteristics change. The CSCR will be made available within the CRMF.

# Healthcare IT Clinical Risk Management Activities

## Hazard Identification

SingFit will conduct hazard identification workshops to identify potential hazards associated with the deployment and use of a healthcare IT system. The CSO will be responsible for facilitating such workshops and ensuring attendance from the Product Team:

The workshops will have minutes taken and a copy stored in the CRMF. If a healthcare IT solution is deemed not to be safety related then this decision will be formally recorded.

All identified hazards will be recorded in the HL.

## Risk Assessment

SingFit will conduct risk assessments in accordance with the Risk Management Plan [\[CRMP\]](#). The HL will be updated to capture the risk assessment.

## Risk Evaluation

SingFit will conduct healthcare IT system risk evaluation in accordance with the Risk Management Plan [\[CRMP\]](#). The HL will be updated to capture the risk evaluation.

## Risk Control

Where the initial risk evaluation is deemed unacceptable, further risk controls will be required. The Organization will manage risks in accordance with the Risk Management Plan [\[CRMP\]](#). Details of the risk control measure and evidence of effective implementation will be captured in the HL.

## Deployment and Ongoing Maintenance

To support clinical safety activities undertaken during any deployment phases of a project or program of work the following documentation will be required to form a part of the overall approval process where there are significant changes are made that will impact the clinical safety related to the platform:

- Change management and release configuration

## Incident Management

Clinical Risk Management activities within SingFit and services offered are outlined within the Clinical Risk Management Plan ([CRMP](#)). As such clinical safety related incidents are dealt with in a similar manner as other incidents within the organization such as financial, reputational, technical and other service impacting categories



# Clinical Safety Competence and Training

## Overview

The clinical safety activities described in this Clinical Risk Management System shall be undertaken by competent staff. Suitable training shall be undertaken by staff to maintain and expand their level of competence.

## Competency

All relevant staff shall be sufficiently competent for the roles and tasks which they are asked to undertake. Where an individual does not have sufficient experience or knowledge then that person shall be monitored, and their work reviewed, by someone who has the necessary competence. Such supervision shall prevail until it is judged that the individual has amassed the necessary experience to undertake such tasks unsupervised.

In assessing competency, the different functional roles required to fully discharge the obligations of the Clinical Risk Management System, and the necessary skills and knowledge needed for each, shall be considered. Primary functional roles may include:

- Conducting discrete safety analyses or defining the Hazard Risk Indicators for a particular project.
- Making a valid judgment on the safety tasks, activities and techniques required for a given product in order to justify the comprehensiveness and completeness of the safety assessment and produce the safety argument with supporting evidence.
- Assurance of safety assessments and healthcare IT software products. Performance of safety techniques and development of the safety argument for a particular healthcare IT software product must be independent of any assurance activities for the same.
- Improving and refining the overall Clinical Risk Management System, for example, audit, process change, quality.
- Ownership and leadership, for example, ultimate safety accountability, culture change, influencing and strategic direction.

The first test in establishing competency shall be at the interview stage where potential staff shall be assessed against the above representative roles and agreed job descriptions. Thereafter, competence shall be monitored through the organization's established appraisal scheme. Any perceived deficiencies identified during the course of the work or at the appraised stage, especially during probation, shall be addressed immediately, for example, through the assignment of a competent supervisor or the provision of suitable training.

## Training

As part of the employment process and thereafter personnel in the clinical safety related positions will undergo suitable training to develop, maintain or enhance their competency level. Such training may include:

- 'on the job' training conducted under supervision

- Internal training courses
- Approved external training courses
- NHS Digital foundation training course (required for the CSO only)

Currently, the CSO provides clinical safety and compliance training to the Chief Clinical Safety Officer, VP, Operations, and the Product and Technology Team. The training consists of an overview of the roles and responsibilities of the clinical safety related staff, clinical safety and risk management policy and procedures as well as documentation. Completion of any safety training shall be recorded by the individual for recordkeeping.

## Audits

### Overview

Audits shall be undertaken to ensure that projects are adhering to the defined safety requirements. Such audits will focus on the clinical safety related teams. As the app currently does not connect to any third party products, third party audits are not required at this time.

### Internal Safety Audits

SingFit shall undertake regular internal safety audits to ensure that projects undertaken within the organization are compliant with this Clinical Risk Management System. These audits shall be conducted and recorded in accordance with the internal quality management procedure.

The scope of an internal safety audit will be the formal Clinical Risk Management System and the Organization's documentation supporting this document.