Clinical Risk Management Plan

This Clinical Risk Management Plan (CRMP) defines the framework to assess and control clinical risk associated with the development, maintenance, and use of the Sensyne Health Platform and associated services.

Document Management
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Approved by: CEO
Document owner: Product Manager

Document Control

Version	Date	Change	Approved By
1.0	08 Jan 2018	Initial version	Product Manager
2.0	08 Jan 2019	Annual review	Product Manager

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Clinical Risk Management Plan

This document describes the Clinical Risk Management Plan (CRMP) for the development, maintenance and use of the Sensyne Health Platform and associated services. It sets out the scope of the clinical risk management activities and the roles and responsibilities to be applied.

Purpose

The purpose of this plan is to define the implementation of a Clinical Safety Management System (CSMS) in accordance with the requirements of DCB0129 and DCB0160 and to demonstrate that Sensyne Health has in place a robust clinical risk management system (CRMS) that ensures that clinical risks associated with the development, maintenance and use of the Sensyne Health Platform are identified, assessed and controlled to a level that is as low as reasonably practicable (ALARP).

This CRMP defines the criteria by which clinical risks will be managed, the roles and responsibilities of those involved in the clinical risk management activities, and the deliverables to be produced as evidence that the CRMS is being applied in practice.

Background to clinical safety standards and requirements

Sensyne Health is required to comply with the clinical risk management requirements of DCB0129 and DCB0160 as a manufacturer of a Clinical Risk Management System (CRMS) and as a provider of clinical services. These requirements are intended to ensure that clinical risks are identified, assessed and controlled in a structured and auditable manner throughout the lifecycle of the system and the services it supports.

Scope

This plan applies to all activities undertaken under Sensyne Health's control that may impact clinical safety, including:

- The design, development, maintenance and use of the Sensyne Health Platform
- Clinical research and analytics services supported by the Sensyne Health Platform
- Interfaces between the Sensyne Health Platform and other systems or services
- Changes to the platform, its interfaces or its supporting processes

Abbreviations and Definitions

Term	Definition
ALARP	As Low As Reasonably Practicable
CSO	Clinical Safety Officer
CSMS	Clinical Safety Management System
DCB0129	Clinical Risk Management: its Application in the Manufacture of Health Care IT by Manufacturers
DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health Care IT by Organisations
DTAC	Digital Technology Assessment Criteria
EPR	Electronic Patient Record
GMC	General Medical Council
HRA	Health Research Authority
IG	Information Governance
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
PMS	Patient Management System
RCA	Root Cause Analysis
SCCI	Standard Contract Clinical Information

Service Overview

Sensyne Health Platform

The Sensyne Health Platform is a cloud-based system that collects, stores and manages clinical research data collected from the management of hospital in-patients and out-patients. It also includes a clinical research application used by clinicians to record research data, and a data analytics module that allows authorised users to analyse and visualise research data. The platform supports the delivery of clinical research studies and analytics services that may inform clinical decision-making and service improvement.

Clinical research

Sensyne Health supports the conduct of non-interventional research by clinicians and research teams using data from the Sensyne Health Platform. Research activities may include recruitment, data collection, analysis and dissemination of results. Clinical safety considerations apply where research outputs are used to inform care pathways, clinical decisions or service delivery.

Interfaces

The Sensyne Health Platform interfaces with a number of external systems and services, including:

- Hospital Patient Management Systems (PMS)
- Electronic Patient Records (EPR)
- Standard Contract Clinical Information (SCCI) feeds
- Identity and access management services
- Analytics and reporting tools

These interfaces are considered in the clinical risk management process where they have the potential to impact clinical safety.

Hosting

The Sensyne Health Platform is hosted on Amazon Web Services (AWS) infrastructure. Hosting arrangements are managed in accordance with information security and data protection requirements, and are subject to ongoing monitoring and review.

Risk Management Process

Risk Management Process

Sensyne Health applies a structured clinical risk management process in accordance with DCB0129 and DCB0160. The process includes:

- Hazard identification
- Risk assessment
- Risk control
- Verification
- Ongoing monitoring and review

Clinical risks are assessed using a 5 x 5 risk matrix. Risks are recorded, prioritised and tracked through to closure in the clinical risk register.

Risk Acceptance Criteria

Risks are accepted only where they are reduced to ALARP. Acceptance of residual risk is proportionate to the severity of harm and the likelihood of its occurrence, taking into account the benefits of the system and the clinical context in which it is used.

Risk Control Measures

Risk control measures may include:

- Changes to the system or its interfaces
- Changes to clinical workflows
- Training and guidance for users
- Monitoring and audit activities

Risk control measures are implemented and verified before the associated risk is considered closed.

Ongoing Risk Management

Risks are reviewed at regular intervals and following any significant change to the system, its interfaces or its supporting processes. Ongoing monitoring includes review of incidents, complaints and feedback where they have a potential clinical safety impact.

Clinical Risk Management Roles

Clinical Risk Management Team

The Clinical Risk Management Team is responsible for the CSMS. It is led by the Clinical Safety Officer (CSO) and includes other roles as required to support the management of clinical risk.

The team ensures that the CSMS is maintained in accordance with the requirements of DCB0129 and DCB0160, supports the identification and assessment of clinical risks, and maintains the clinical risk register and related documentation.

Clinical Safety Officer (CSO)

The Clinical Safety Officer (CSO) is responsible for the CSMS and for the clinical risk management activities associated with the development, maintenance and use of the Sensyne Health Platform. The CSO is responsible for:

- Maintaining the CSMS
- Reviewing clinical risk assessments
- Escalating clinical risks where appropriate
- Supporting the assessment of clinical safety impact of changes to the platform

The CSO acts independently in the assessment of clinical risk and may escalate concerns to senior management where they consider that risks are not being managed in accordance with the CSMS.

Clinical Risk Management Lead

The Clinical Risk Management Lead supports the CSO in the day-to-day management of clinical risk. This includes maintenance of the clinical risk register, preparation of risk assessments, and coordination of clinical risk activities across the development and support teams.

Clinical Risk Management Team

The Clinical Risk Management Team supports the CSMS by carrying out clinical risk assessments, maintaining documentation, and supporting the implementation of risk control measures. The team includes clinical and technical expertise as required to support the assessment and management of clinical risks.

Clinical Risk Management Activities

Clinical Risk Management Process

The Clinical Risk Management Process applies the principles of DCB0129 and DCB0160 to identify, assess and control clinical risks associated with the development, maintenance and use of the Sensyne Health Platform. It includes activities to identify hazards, assess the associated risks, implement control measures, and verify that those controls are effective.

Hazard Identification

Hazards are identified through a structured review of the system, its interfaces and its supporting processes. Sources of information include design reviews, clinical workflows, incidents, complaints and feedback. Hazards are recorded in the clinical risk register and assessed for their potential impact on patient safety.

Risk Assessment

Each identified hazard is assessed using a 5 x 5 risk matrix, taking into account the severity of harm and the likelihood of its occurrence. The assessment considers the clinical context in which the system is used and the intended users of the system.

Risk Control

Risk control measures are proposed to reduce the risk to ALARP. Controls may include changes to the system, its interfaces or its supporting processes, training and guidance for users, or changes to clinical workflows. Control measures are recorded against the relevant hazard in the clinical risk register.

Verification

Risk control measures are verified before the associated risk is considered closed. Verification may include testing, review or audit, depending on the nature of the control and the risk it addresses.

Ongoing Monitoring

Risks are reviewed at regular intervals and following any significant change to the system, its interfaces or its supporting processes. Ongoing monitoring includes review of incidents, complaints and feedback where they have a potential clinical safety impact.

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Clinical Risk Management Deliverables

Clinical Risk Management Plan

This document. It defines the scope, roles and responsibilities, and the activities to be applied in the management of clinical risk.

Clinical Safety Case

A document which sets out the clinical safety case for the Sensyne Health Platform and its services. It summarises the clinical risk management activities and supports the assessment of clinical safety for the platform.

Hazard Log

A record of identified hazards. It includes the clinical risks related to hazards, the associated risk assessments, and the control measures applied. The hazard log is maintained as part of the clinical risk register.

Clinical Safety Case Report

A document which sets out the clinical safety case for a specific release, deployment or change to the platform. It supports the assessment of clinical safety for that release and records the evidence that the relevant controls have been applied and verified.

Clinical Risk Management Plan review process

The Clinical Risk Management Plan is reviewed at regular intervals and following any significant change to the platform, its interfaces or its supporting processes. The review includes:

- Changes to roles and responsibilities
- Changes to the clinical risk management process
- Changes to the clinical risk register
- Changes to the platform or its interfaces

Updates to the plan are recorded in the document control table and approved by the CSO.

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