Clinical Safety Case Report

**Clinical Safety Case Report TEMPLATE**

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**Updates**

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| New Version Number | Date | Change  |
| V1 | 13.09.2021 | Independent quality review of draft document to include consistency, branding changes and alignment to local ICS programme methods |
|  V2 | 12.02.2024 |  Review of template, change of branding.  |
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| Document filename:  |
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Document Management

Revision History

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| Version | Date | Summary of Changes |
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Related Documents

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

| Ref  | Doc Reference Number | Title | Version |
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# Introduction

Purpose of the Clinical Safety Case Report and phase of lifecycle it relates to.

# System Definition / Overview

Description of the Health IT System; identification of Health IT System part and version number; description of the clinical environment it is to be used in; description of any existing systems it replaces or interfaces with; number of users and patients.

# Clinical Risk Management System

Description of the Manufacturer’s clinical risk management system; identification of key personnel, their roles and responsibilities; identification of clinical risk management governance structure.

# Clinical Risk Analysis

Hazard identification; description of patient safety consequences; explanation of hazard causes and contributory conditions; identification of existing mitigating controls; estimation of clinical risk; identification of participating personnel.

# Clinical Risk Evaluation

Evaluation of initial level of risk of each identified hazard using pre-defined criteria.

## Clinical Risk Control

Identification, justification, implementation and verification of adequate risk controls; residual clinical risk evaluation and completion of controls.

## Hazard Log

Presentation of associated Hazard Log.

# Test Issues

Summary of any outstanding test issues and the impact on clinical safety.

# Summary Safety Statement

Statement from the Clinical Safety Officer summarising the safety position of the Health IT System in the context of the intended deployment.

# Quality Assurance and Document Approval

Evidence of appropriate quality, review, and approval regimes.

# Configuration Control / Management

Evidence of appropriate configuration control being used.