Clinical Safety Case Report

**Clinical Safety Case Report TEMPLATE**

|  |  |
| --- | --- |
| Version Number: | 2.0 |
| Author (name) | Paul Warwick |
| Name of approving committee | Interweave Management Board |
| Date Issued: | 12.02.2024 |

**Updates**

|  |  |  |
| --- | --- | --- |
| 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. |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Document filename: | | | |
| Directorate / Programme |  | Project |  |
| Document Reference | |  | |
| Director |  | Status |  |
| Owner |  | Version |  |
| Authors |  | Version issue date |  |

Document Management

Revision History

|  |  |  |
| --- | --- | --- |
| Version | Date | Summary of Changes |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Reviewers

This document must be reviewed by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer name | Title / Responsibility | Date | Version |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Approved by

This document must be approved by the following people:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Title | Date | Version |
|  |  |  |  |
|  |  |  |  |

Related Documents

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

| Ref | Doc Reference Number | Title | Version |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Contents**

[Introduction 4](#_Toc158640442)

[System Definition / Overview 4](#_Toc158640443)

[Clinical Risk Management System 4](#_Toc158640444)

[Clinical Risk Analysis 4](#_Toc158640445)

[Clinical Risk Evaluation 4](#_Toc158640446)

[Clinical Risk Control 4](#_Toc158640447)

[Hazard Log 4](#_Toc158640448)

[Test Issues 4](#_Toc158640449)

[Summary Safety Statement 4](#_Toc158640450)

[Quality Assurance and Document Approval 4](#_Toc158640451)

[Configuration Control / Management 4](#_Toc158640452)

# 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.