Clinical Safety Case Report

TRIANGLE CONSULTING : STAR ONLINE

Document Management

Revision History

Version	Date	Summary of Changes	Updated by
v0.1	17/06/2023	Draft	Karen Whitton CSO
V1.0	03/17/2023	Version 1 completed for review and approval	Karen Whitton CSO

Reviewers

This document must be reviewed by the following people:

Version	Reviewer name	Title / Responsibility	Date
V1.0	Sarah Owen	Director	03/07/2023

Clinical Safety Officer (or predetermined delegate) approval

Version	Name	Role	Date
v0.1	Karen Whitton	Clinical Safety Officer	draft
V1.0	Karen Whitton	Clinical Safety Officer	03/07/2023

Related Documents

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

#	Title	Version
1	Clinical Risk Management: its Application in the Manufacture of Health IT Systems - Specification	4.2
2	DCB0160: Clinical Risk Management: It's Application in the Deployment and use of Health IT Systems	3.2
3	DCB0129 Implementation Guidance v3.2.docx	3.2
4	Triangle Consulting Star Online Hazard Log	1.0
5	Triangle Consulting 'Star Online' Clinical Risk Management Plan	1.0
6	Triangle Consulting Star Online Safety Incident Management Log	N/A
7	Triangle Consulting 'Star Online' Clinical Safety Case	N/A
8	Triangle Consulting Clinical Risk Management System	1.0
9	Clinical Safety Team Competency Log	N/A
10	Outcomes Star Online_Clinical Incident Mgmt Policy June 23	1.0
11	Outcomes Star Online SDLS	V1.0
12	Star Online_Change Management process_February 2023	1.0
13	Outcomes Star Online Intended Use Statement	1.0

Contents

Definitions

Term	Definition
Clinical Safety Officer	Person in a Manufacturer's organisation responsible for ensuring the safety of a Healthcare Solution in that organisation through the application of clinical risk management.
Clinical risk	Combination of severity of harm and the likelihood of occurrence of that harm.
Clinical risk analysis	Systematic use of available information to identify and estimate a risk.
Clinical risk control	Process in which decisions are made and measures implemented by which clinical risks are reduced to, or maintained within, specified levels.
Clinical risk estimation	Process used to assign values to the severity of harm to a patient and the likelihood of occurrence of that harm.
Clinical risk evaluation	Process of comparing a clinical risk against given risk criteria to determine the acceptability of the clinical risk.
Clinical risk management	Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling clinical risk.
Clinical Risk Management File	Repository of all records and other documents that are produced by the clinical risk management process
Clinical Risk Management Plan	A plan which documents how the Manufacturer will conduct clinical risk management of a Healthcare Solution.
Clinical Risk Management Process	A set of interrelated or interacting activities, defined by the Manufacturer, to meet the requirements of this standard with the objective of ensuring clinical safety in respect to the development and modification of a Healthcare Solution.
Clinical safety	Freedom from unacceptable clinical risk to patients.
Clinical Safety Case	Accumulation and organisation of product and business process documentation and supporting evidence, through the lifecycle of a Healthcare Solution.
Clinical Safety Case Report	Presents arguments and supporting evidence that provides a compelling, comprehensible, valid case that a system is safe for a given application in a given environment at a defined point in a Healthcare Solution's lifecycle.
Customer Organisation	A Health Organisation which has deployed, or will be deploying the Healthcare Solution
Harm	Death, physical injury, psychological trauma and/or damage to the health or well-being of a patient.

Hazard	Potential source of harm to a patient.
Hazard Log	A mechanism for recording and communicating on-going identification and resolution of hazards associated with a Healthcare Solution.
Health Organisation	Organisation in which a Healthcare Solution is deployed or used for a healthcare purpose.
Healthcare Solution	Product used to provide electronic information for health or social care purposes. The product may be hardware, software or a combination.
Initial clinical risk	The clinical risk derived during clinical risk estimation taking into consideration any retained risk control measures.
Intended use	Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer to customers.
Issue	The process associated with the authoring of a document. This process includes: reviewing, approval and configuration control.
Likelihood	Measure of the occurrence of harm.
Lifecycle	All phases in the life of a Healthcare Solution, from the initial conception to final decommissioning and disposal.
Manufacturer	Person or organisation with responsibility for the design, manufacture, packaging or labelling of a Healthcare Solution, assembling a system, or adapting a Healthcare Solution before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.
Patient	Person who is the recipient of healthcare.
Patient safety	Freedom from harm to the patient.
Post-deployment	That part of the lifecycle of a Healthcare Solution after it has been manufactured, released, deployed and is ready for use by the Health Organisation.
Procedure	Specified way to carry out an activity or a process.
Process	Set of interrelated or interacting activities which transform inputs to outputs.
Release	A specific configuration of a Healthcare Solution delivered to a Health Organisation by the Manufacturer as a result of the introduction of new or modified functionality.
Residual clinical risk	Clinical risk remaining after the application of risk control measures.
Safety incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.
Safety Incident Management Log	Tool to record the reporting, management and resolution of safety incidents associated with a Healthcare Solution.
Severity	Measure of the possible consequences of a hazard.

Third party product	A product that is produced by another organisation and not by the Healthcare Solution manufacturer. Examples include operating systems, library code, database and application servers and network components.
The Organisation	The generic term used for the organisation that is the prime owner and responsible for the clinical safety of the Healthcare Solution
Top Management	Person or group of people who direct(s) and control(s) an organisation and has overall accountability for a Healthcare Solution.

Executive Summary

This report is written in support of the Triangle Consulting Star Online software and in conjunction with the manufacturer to ensure compliance with appropriate standards as outlined below. This is a working document to be maintained by the named personnel and must be approved by the CSO to meet regulatory requirements.

This document is specific to compliance with DCB0129: 2018 and has been prepared in line with the Triangle Consulting Quality Management System and the Star Online Risk Management Plan.

The Star Online system has undergone robust safety assessment, which continues throughout each phase of development and deployment. It has been assessed against criteria defined in the CRMP. The determination of the CSO, Top Management and the CST is that the current version of the system has a safety profile which is acceptable. The residual clinical risk is summarised in the table below: The output of the clinical risk assessment is summarised in the table below:

Table 1:

Initial	Residual	Risk rating	Definition
0	0	5	Unacceptable level of risk.
0	0	4	Mandatory elimination or control to reduce risk to an acceptable level
1	0	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.
7	6	2	Acceptable where cost of further reduction outweighs benefits gained.
5	7	1	Acceptable, no further action required

Hazards requiring mitigation identified: A total of 13 hazards were identified. One hazard identified was estimated with an initial risk rating of >2, and therefore were all subject to risk control measures in line with the acceptability criteria defined in the CRMP. All remaining hazards were also mitigated to be 'As Low As Reasonably Practicable' (ALARP, appendix 5), and therefore the overall risk was further reduced.

The residual risk of all hazards following implementation and verification of risk control measures were estimated within the acceptability criteria and it was determined that it was not possible and/or practicable to implement any further measures. The risk management process is live throughout the lifecycle of the product, and therefore further control measures may be implemented at appropriate times of development. As such, the safety of the system is not dependant on any open actions documented in the Hazard Log.

Introduction

This report documents the analysis of a formal and structured clinical safety assessment of the current version of Triangle Consulting Star Online web based tool. This CSCR forms part of the clinical risk management system (CRMS: ref 8) and presents the supporting evidence to reflect the safety of the product. It follows the guidance and fulfils the requirements of DCB0129, Clinical Risk Management: its Application in the Manufacture of Health IT Systems (ref 1). This document relates to the current deployed version of the Star Online. It will be routinely reviewed and updated to reflect changes and subsequent releases. It evidences that all foreseeable hazards have been documented and evaluated by the multidisciplinary Clinical Safety Team and each hazard has been mitigated to a level which is as low as reasonably practicable (ALARP: appendix 5).

Triangle Consulting Social Enterprise is an innovative, mission-led organisation who have developed the outcome measurement tool Outcomes Star™ and the Star Online to support its use. The Star Online has been designed to digitise the use of the Outcomes Star™.

The Outcomes Stars™ are a family of evidence-based tools designed to both support and measure change when working with people. Triangle Consulting licence their use and provide training to customers. There are currently over 50 versions of the star, each supporting different needs. Each version consists of a set of scales presented in a friendly, accessible star shape covering the key outcome areas that are relevant to that sector. It

provides a collaborative in engaging service users in achieving their outcomes by using a highly visual, person centred and simple to use product.

It is currently used across a wide range of sectors, providing the service to approximately 1200 customers at present.

Scope

The scope of this document and assessment does not include information security and information governance areas – these are covered by separate dedicated risk processes within the organisation. This document relates to the current deployed version of Star Online. It will be routinely reviewed and updated to reflect changes and subsequent releases.

This report is based on the assessment of Star Online to meet the requirements of standard DCB0129 (ref 1). Each deploying organisation must meet their own requirements to carry out their risk assessment in compliance with DCB0160 (ref 2). This ensures a robust safety assessment of the product in relation to each use case and deployment. This report does not provide assurance of compliance with any other regulatory standards.

The The Outcomes Star™ is an evidence based tool which the Star Online provides digital support for. This report does not seek to evidence the validity or research around the tool itself and only provides assurance as to the safety of the digital product.

System Definition / Overview

The Star Online is the digital home of the Outcomes Stars, supporting organisations to use the Stars in proving and improving the outcomes achieved with the people they support. The Star Online is a web application that allows to access Outcomes Star resources and guidance, record Star data and service user information, and report on outcomes. It has been designed for frontline services - practitioners, managers and funders – using any version or versions of the Outcome Stars™ to support and measure change when working with people.

The Star Online provides users with the following functions:

- Collaborative completion of the Outcomes Star™
- Retrospective completion of the Outcomes Star™ (when users have completed the paper format with the service user)
- Setting and management of service user Action Plans and goals
- Caseload management
- Service user notes/record keeping
- Creating new service user records
- Reporting
- Dedicated helpdesk

Intended use

The risk assessment activities described in this report have been undertaken in association to the intended use of the platform. The intended use/purpose of Star Online is detailed fully in the Outcomes Star Online Intended Use Statement (ref 13) and summarised below:

- **Description**: as defined in 'System Definition/Overview' above
- **Intended purpose:** To support frontline services in their support of people by:
    - recording basic profile information and information about support and services provided to that person
    - completion of Outcomes Star assessments, including recording Star data and action planning
    - report creation
    - providing Outcomes Star resources
- **Intended users:** Users of the software are:
    - Direct Users: Account Leads, Service Managers/Practitioners, Integration Leads
    - Other Users: People being supported (do not have direct access), Analysis or other data stakeholders
- **Clinical Indications:** Sectors, services and support needs where Outcomes Star Online is used:
    1. Adult care
    2. Armed forces and veterans
    3. Autism and ADHD

4. Criminal justice
5. Disaster recovery
6. Domestic abuse
7. Education
8. Employment
9. Families and children
10. Health – general well-being; managing long-term conditions
11. Housing and homelessness
12. Mental health
13. Refugee and asylum seeking
14. Substance misuse
15. Youth

Each version of the Outcomes Star assessment/measurement tool is tailored to the needs of a sector and the service users they support.

• **Contraindications:** Organisations and users should use judgement (in association with support from Triangle) to ensure the correct Star version is the right tool for their service users. Various methods of Star completion are available and should be considered if the Star Online is deemed unsuitable. It is intended that organisations will use Outcomes Star Online alongside other case management software, other record management software and other data analysis software, as required by each organisation. The Outcomes Star Online does not intend to be used as a full case or records management system.

• **Intended environment**: Professional settings, dependent on user need, eg. office environments.

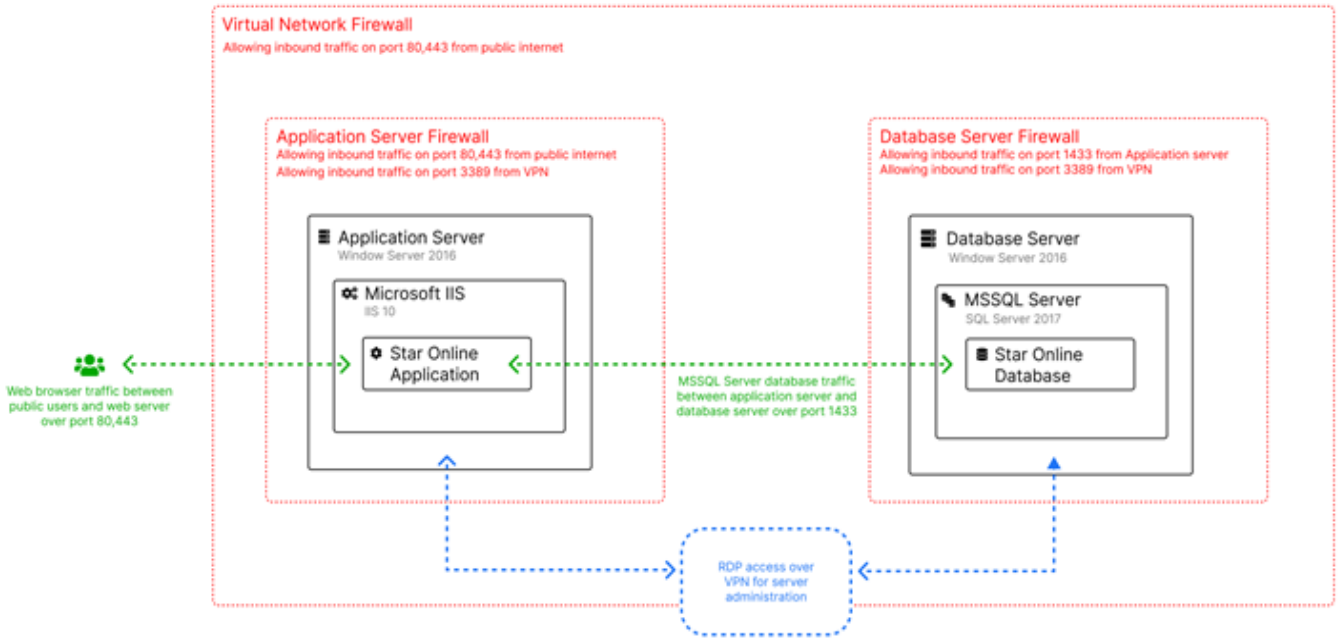
Technology and Architecture

The technology and architecture of the system is fully described in the Outcomes Star Online Technical Information (ref 14). Microsoft Azure cloud based servers are utilised to ensure system resilience and security assurance through compliance with regulatory standards.

Third party components (third party components were considered in the scope of the clinical risk assessment):

- SendGrid for system emails (sign up, 2FA code etc)
- HiCharts for charts in report dashboards

Technical security diagram:



Software Development Lifecycle

Triangle Consulting follows an agile development software lifecycle strategy as detailed in ref 10. Clinical Risk Management has been incorporated into the lifecycle as per the diagram below:

Testing Strategy

All software development by Triangle Consulting is subject to a robust, structured testing strategy, as detailed in the Outcomes Star Online_Testing Strategy June 23. Testing is conducted in a variety of development/test environments prior to live deployment and use. A summary of the testing process is as follows:

1. Initial Unit and Integration Testing
2. Development of Testing Scripts
3. System and Regression Testing
4. User Acceptance Testing (UAT)
5. Smoke Testing
6. Defect Management
7. Penetration Testing (a minimum of annually)

Clinical Risk Management System

The clinical risk management of the system (CRMS: ref 8) is overseen by the CSO appointed by the company. In accordance with the DCB0129 (ref1) standard, the CSO must be a registered clinician who is appropriately trained and experienced in clinical risk management. Triangle Consulting have chosen to contract the clinical safety officer and clinical risk management services of 8Fold Governance Ltd, whos team supports Triangle Consulting to meet the mandatory requirements for DCB0129, covering all aspects including establishing the clinical safety management process, producing required documentation, including this report and providing a qualified named CSO.

The CSO facilitates the clinical risk management activities with the support of a multidisciplinary Clinical Safety Team which they lead (documented in the table below). This includes individuals from within Triangle Consulting with expertise and seniority on the technology used, software development processes and lifecycle, quality control, the clinical use cases, and usage of the system by the end users.

The team is responsible for considering clinical safety within their respective areas of expertise. In conjunction with the CSO they ensure that every release of the software undergoes a formal review to ensure all requirements of the standard have been met. Further details on team membership, competencies and responsibilities are recorded in the Clinical Risk Management Plan.

In addition, consideration of clinical safety is inculcated in all relevant employees. All members of the clinical safety team as well as other key staff undergo internal training from the CSO on the basics of clinical risk management so that patient safety is a key consideration throughout the lifecycle of the system.

Key personnel, roles and responsibilities

Table 1:

Name / role	Responsibilities
Karen Whitton	• Leads the Clinical Safety Team overseeing the risk management of the system • Ensures that the Clinical Risk Management Plan is followed

Clinical Safety Officer karen@8foldgovernance.com	• Ensures that staff are adequately trained to perform their duties as required by the plan • Signs off on the clinical safety of each release • Keeps clinical safety documentation up to date (Clinical Safety Case Report, Clinical Safety Management Plan, Hazard Log, Safety Incident Management Log) • Periodically audits processes to ensure they are being followed • Is adequately certified for the role of CSO as required by DCB0129 • Raise any unacceptable hazards with top management • Monitor and evaluate incidents during post deployment phase
Sarah Owen Product Director	• Contributes to the risk analysis process • Approval of Clinical Safety documentation • Raise any unacceptable hazards with top management • Monitor and evaluate incidents during post deployment phase • Attends regular clinical safety meetings
Emily Lamont	• Contributes a technical/development perspective • Raise any hazards identified to the CSO • Implementation of technical hazard mitigations • Ensures clinical safety is considered at each stage of development • Attends regular clinical safety meetings - brings all issues for release to be reviewed • Reactive review of low risk interim fixes/patches at following CS meetings

Helen Bacon Implementation Lead	• Contributes to the risk analysis process • Raise any identified hazards to the CSO • Monitor and evaluate incidents during post deployment phase • Attends regular clinical safety meetings: bring user feedback and clinical incident reports to CS meetings for review • Clinical Incident monitoring • Ensures appropriate incident reporting procedures are implemented in line with the CRMP
Anna Good Head of Research	• Contributes to the risk analysis process • Raise any identified hazards to the CSO • Monitor and evaluate incidents during post deployment phase • Attends regular clinical safety meetings: bring user feedback and clinical incident reports to CS meetings for review • Clinical Incident monitoring • Ensures appropriate incident reporting procedures are implemented in line with the CRMP

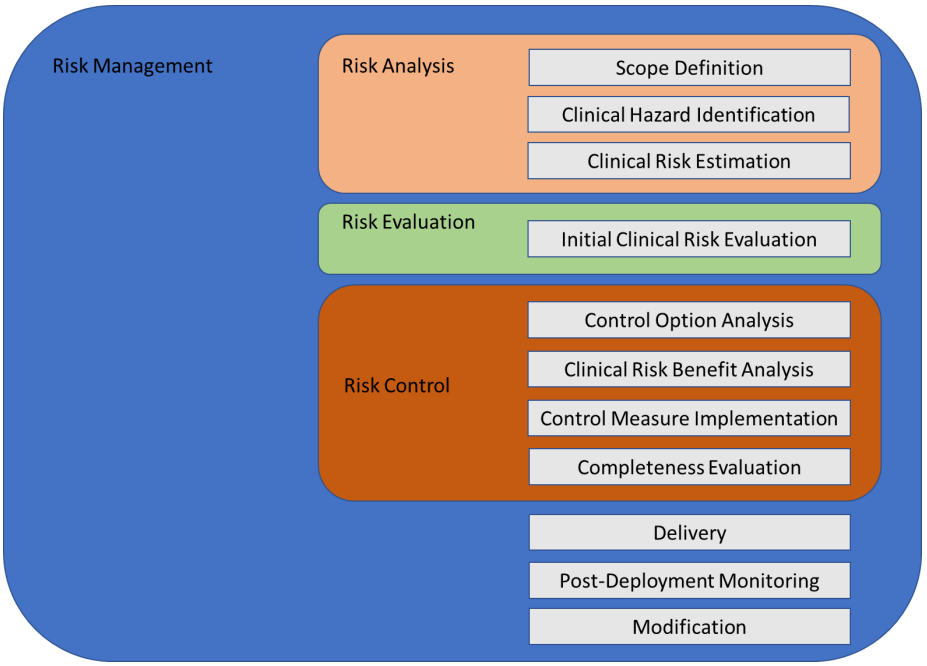
Clinical Risk Management Activities

Triangle Consulting has, and will continue to conduct hazard identification workshops to identify potential hazards associated with the deployment and use of the Star Online system. The CSO and Product Director are responsible for facilitating such workshops and ensuring attendance from appropriate representatives. The risk management activities were conducted in accordance with with the CRMP. Hazard workshops are most commonly initiated during the design phase of development of new system functionality.

Clinical Risk Analysis and Evaluation

Triangle Consulting conduct clinical risk analysis and evaluation as part of their risk management activities described in the CRMS and CRMP and detailed below in the risk management strategy approach recommended by NHS Digital:

Fig 5: NHSD Risk Management Process



For the initial clinical safety review the CSO and clinical safety team walked through the User Interfaces, stepping through all user flows. The technical architecture of the software development life-cycle and testing procedures were reviewed. Consideration was given to the deployment, intended use and training in use of the system. Details of all hazard workshops are recorded in the table below:

Table 3:

Date	Purpose	Attendees	Summary
15/02/23	1. System demo and user flow	CSO and CST	1. The system was demo's in it's current entirety to the CST and CSO for clinical risk analysis. Including providing Scope

	2. Clinical Risk Management Training		Definition for RM activities 2. Risk Management and DCB0129 training provided by CSO to CST
22/03/23	Hazard Workshop	CSO and CST	Clinical Hazard Identification. Identification of existing control measures and potential additional controls The output was recorded in the SWIFT analysis worksheet. The CSO transcribed in further detail into the Hazard Log.
19/03/23	Hazard Workshop	CSO and CST	1. Risk estimation 2. Control option analysis 3. Risk evaluation The Hazard log was fully reviewed by the team. Risk ratings were applied and additional control measures prioritised for implementation. The CSO then compiled an actions log for prioritisation of control measure implementation and verification of existing (and additional) controls.
16/06/23	Completeness Evaluation	Karen Whitton Sarah Owen	Control measures have been implemented according to priority. Verification of controls completed and recorded in the Hazard Log, with evidence made available in the CRMF to the CSO. Minor control measures (low priority actions) have been added to the product roadmap for future development. Structured approach to ongoing adherence to the CRMP has been implemented: Clinical safety review meetings will be held on a monthly basis.

The system was broken down into its constituent business processes and functionalities. Each was subjected to a SWIFT analysis with consideration given to normal conditions,

fault conditions and reasonably foreseeable misuse. This looked at what could go wrong and any mitigations and controls in place for these.

The set of issues thus identified was consolidated into a number of hazards. A risk analysis was conducted for each of these taking into consideration the controls in place. The team identified further controls that could be added to reduce the risk further. These were prioritised and implemented.

Hazard Log & Clinical Risk Control

Full details of all hazards, controls and completed actions are documented in the Hazard Log.

The Clinical Safety Team identified 13 hazards with potential clinical impact. These were evaluated using the criteria defined in the CRMP. Risk control measures were implemented in line with the ALARP (appendix 5) principle. The safe application and use of the system is dependent on customer organisations and users complying with the transferred control measures identified in the hazard log as detailed below. The identified hazards are summarised in the table below:

Table 4:

Hazard ID	Description	Residual Risk Rating	Transferred Controls
HAZ001	**Patient Identification Error**	2	Users must adhere to local record keeping policies.
HAZ002	**User cannot access patient record**	1	N/A
HAZ003	**Inappropriate Star Version is used**	1	N/A
HAZ004	**Paper star entry is incorrect**	2	Users must adhere to data quality standards and local record keeping process

HAZ005	**Data is entered into incorrect free entry data field**	1	N/A
HAZ006	**Star entry is associated with incorrect SU 'engagement'**	1	N/A
HAZ007	**Action/goal is not saved to record**	2	N/A
HAZ008	**Goal reminder date/alert is not set**	1	N/A
HAZ009	**Data Breach**	2	Users are managed by Account Leads - services must develop internal procedures for leavers and movers
HAZ010	**Data deleted or amended inappropriately**	2	Users must comply with local record keeping policies
HAZ011	**Safeguarding concern not managed**	2	Services must document and follow their internal safeguarding procedures. Star Online is not intended for the reporting and escalation of safeguarding issues
HAZ012	**Psychological distress**	1	Professional judgement of the practitioner
HAZ013	**Third Party Failure**	1	N/A

Configuration Control/ Management

The Star Online team follows an agile development process. Trello is used by the product for managing and tracking changes to the software. Following scoping, specification and hazard identification, the product team then raise each issue for development in Azure Dev Ops, where the technical implementation and testing process is managed. The Clinical Safety Team meets on a regular monthly basis to formally review open 'BAU'

tickets such as bug fixes and minor iterative changes. Change control follows a structured process as described in the Change Management Procedure.

All functional changes to the system undergo clinical safety review in accordance with the CRMP.

Test Issues

System defects are detected and resolved routinely through the testing strategy and agile SDLC. Issues may be detected during testing or as reported by users. All bug tickets are investigated and prioritised based on priority, including clinical safety impact.

At the time of writing, there are 11 open issues for resolution. Low priority issues are marked for resolution routinely. Medium and high priority issues are as follows:

Issue	Impact	Priority
7795 - 2FA codes > users entering correct codes > not being accepted after selecting sign in	Edge case only affecting small number of users - investigating root cause, potentially linked to timezone & timeout. No risk of data loss, but potential risk of interruption to service provision.	High
7689 - Edit SU page> User able to unlink a service user from a service when SU only linked to 1 service	Potential risk of interruption to service provision, as SU record will not appear where user expects. Can be rectified with data fix if record if required ahead of bug fix. No risk of data loss as record remains within service.	Medium
7803 - Completed Star not showing Edit Star or Request Star Deletion buttons. Specific to 1 Star entry only	Edge case only affecting one user - investigating root cause. Limited risk of interruption to service provision or data becoming out of date/inaccurate. Potential for data fix if bug fix not applied in next release.	Medium

Clinical Safety Incident Management

Triangle Consulting have established and documented incident management and

adverse incident reporting processes in place. Relevant documents are referenced at the beginning of this document. All clinical incidents and near miss events are reviewed routinely by the CSO and CST, on a monthly basis. Mechanisms are in place for urgent escalation to the CSO and Top Management where the level of risk determines urgency. This is defined in the incident management decision tree in the incident management procedure.

Summary Safety Statement

The safety of Star Online has been assessed by the CSO and the multidisciplinary Clinical Safety Team in line with the CRMP and DCB0129 guidance. All identified hazards have been evaluated and reduced in line with ALARP principle and are all within the risk acceptability criteria defined by the NHS. All evidence has been reviewed and is contained in the CRMF with all key documents required to meet the relevant standards and will be made available to customer organisations prior to deployment of the software.

Processes are in place to monitor for incidents and review the safety case in light of new evidence if necessary. The safety case will be routinely reviewed through regular meetings of the CST and all key documents approved prior to updates and new releases.

The safety case of Star Online is based on the following assumptions and dependencies:

- It is assumed that deploying healthcare organisations will utilise the information in this Clinical Safety Case Report to ensure the safe deployment and use of Triangle Consulting Star Online. It is recommended that NHS sites refer to the NHS standard “DCB0160:2018 – Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems”. This report should be used as an input to the DCB0160 deployment and use risk assessment.
- A dependency and assumption for the safe intended use of Star Online are that Star Online is not intended by Triangle Consulting to be used in place of expert clinical judgement and decision making. Clinicians should always verify the information provided by Star Online before making clinical decisions.

Following a structured and rigorous clinical safety assessment, led by appropriately trained personnel, and with broad, senior company engagement the evidence demonstrates that the Triangle Consulting Star Online has a safety profile that is deemed acceptable, with all hazards mitigated to be As Low As Reasonably Practicable. There are

no known hazards that have been identified as being a significant or high clinical safety risk.

The CSO and Clinical Safety Team identified some areas for improvement in processes. The safety of the system is not dependent on these, however it is the recommendation of the CSO to implement them when appropriate in order to achieve the best outcomes and adhere to best practice. As such, all outstanding actions are recorded in the Hazard Log and included in the product roadmap.

Quality Assurance and Document Approval

All clinical risk documentation needs to be subject to configuration control so that any subsequent changes can be tracked. The key documents are maintained in the CRMF. The CSO and Triangle Consulting top management must approve the CRMP, Hazard Log and CSCR prior to any future release.

Appendix: Risk Classification Matrix

1. 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
		Consequence				

2. Risk Matrix key - Severity

5	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level
4	
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

3. Hazard likelihood definitions

Likelihood Category	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

4. Hazard Consequence definitions

Consequence 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

5. ALARP Triangle