Clinical Risk Management System

Mobio Interactive Pte Ltd

Published 2020-07-17

Document filename: MI Clinical Risk Management System (CRMS)	
Directorate / Programme:	**AmDTx**
Document Reference:	**CRM-CRMS**
Director	**Bechara Saab**
Owner	**Mark Thoburn**
Authors: Ramya Loganathan, Avetis Muradyan, Bechara Saab, Mark Thoburn	**2020-06-01**

Document Management

Revision History

Version	Date	Summary of Changes
0.1	2020-06-01	Draft 1
1.0	2020-07-17	Approved and updated with references to MI's post release monitoring tools

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
Mark Thoburn	Clinical Safety Officer	2020-07-17	1.0
Bechara Saab	Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer	2020-07-17	1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Mark Thoburn	Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer	2020-07-17	1.0

Related Documents

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

Ref	Doc Reference	Title	Version
1	MIDP	MI Data Policies	1.0
2	AM-CRMF	AmDTx Clinical Risk Management File (CRMF)	1.0
3	CRM-CRMP	MI Clinical Risk Management Plan	1.0
4	CRM-CSHL	AmDTx Clinical Safety Hazard Log	1.0
5	CRM-CSCR	Am MI Clinical Safety Case Report	1.0
6	MSURF	Making Sense of User Feedback	2.0
7	RWD	Psychobiometric Outputs	Sample 2020-07-19

Contents

Introduction

This Clinical Risk Management System (CRMS) outlines the processes to be followed to ensure that all MI products**,** including AmDTx (also “Am”), are developed, implemented and used in a safe manner.

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

This CRMS will be reviewed annually and maintained in MI’s secure document management system.

Purpose

The aim of the CRMS is to ensure that MI staff involved with the development, implementation and use of **AmDTx** are aware of the activities that are required to be undertaken to ensure risks are minimised and controlled when AmDTx is used by patients and health systems.

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

- changes in working practices have been considered
- issues identified though an established internal audit programme 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 MI staff involved in ensuring the safety of MI’s healthcare IT systems, products and services.

Scope

This applies to AmDTx and to all subsequent updates or upgrades. The policy also applies to any local customisations or specific configurations made to AmDTx by MI.

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) for clarification. This nominated person provides clinical and organisational leadership on healthcare IT Patient Safety on behalf of the Organisation.

Definitions

CSO: Clinical Safety Officer - the person responsible for ensuring that MI's Clinical Risk Management System is applied to all clinical systems. MI's CSO is responsible for ensuring the safety of a healthcare IT system through the application of clinical risk management. The CSO ensures that the processes defined by the clinical risk management system are followed.

Healthcare IT Clinical Risk Management (CRM) Governance Arrangements

The responsibility for **AmDTx**' CRM within MI resides with the Clinical Safety Officer.

Organisational management of healthcare IT related risks is as per the existing management arrangements as specified in MI Data Policies.

Clinical Risk Management Team

- Bechara Saab, Chief Scientist (member of Safety Board)
- Mark Thoburn, Chief of Design and Regulatory Affairs, serving as Clinical Safety Officer (member of Safety Board)
- Avetis Muradyan, Chief Technology Officer (member of Safety Board)
- Ramya Loganathan, Security Officer (member of Safety Board)

Governance

Governance for patient safety within MI is provided through the following forums:

Clinical Risk and Safety Board

- Composed of a multi-disciplinary team whose responsibilities include clinical safety.
- Members Attend Clinical Risk and Safety Meetings.

Clinical Risk and Safety Meetings:

- Attended by members of the Clinical Risk and Safety Board.
- Regular meetings held quarterly.
- Extraordinary meetings are held within a week of the identification of a Risk level 3, and within 3 days of the identification of a Risk Level 4 or 5.

Healthcare IT Clinical Risk Management Deliverables

Clinical Risk Management File

MI has established a Clinical Risk Management File (CRMF) for AmDTx, composed of the AmDTx Clinical Safety Hazard Log (CSHL) and the Am MI Clinical Safety Case Report (CSCR). The purpose of the CRMF is to provide a central repository where all safety related information pertaining to AmDTx is stored and controlled.

Clinical Risk Management Plan

MI has established a Clinical Risk Management Plan (CRMP) for AmDTx. 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

MI has established and maintains a Hazard Log (CSHL) for AmDTx. The CSHL is controlled and configured in accordance with MI's document control / quality management policy. The CSHL is available within the CRMF. The purpose of the CSHL is to manage the effective resolution and communication of hazard risk within MI.

Clinical Safety Case Report

MI has issued a Clinical Safety Case Report (CSCR) for Am. The CSCR supports the deployment of AmDTx and will be updated during the lifecycle of AmDTx should the safety characteristics of the device change. The CSCR is controlled and configured in accordance with MI's document control policy. The CSHL will be made available within the CRMF.

Healthcare IT Clinical Risk Management Activities

Hazard Identification

MI conducts hazard identification workshops to identify potential hazards associated with the deployment and use of AmDTx. The CSO is responsible for facilitating such workshops and ensuring attendance from appropriate representatives. Typically, representatives from the following domains will be required:

- Development
- Clinical Research

The workshops will have minutes taken and a copy stored in the CRMF. If AmDTx is deemed not to be safe, then this decision will be formally recorded.

Where any third-party components are used in AmDTx then they will be considered in the scope of the hazard identification activities and subsequent risk assessment. Where none are used a positive declaration to this effect will be recorded in the minutes.

All identified hazards will be recorded in the CSHL.

Risk Assessment

MI conducts risk assessments in accordance with the CRMP. The CSHL will be updated to capture the risk assessment.

Risk Evaluation

MI will conduct healthcare IT system risk evaluation in accordance with the CRMP. The CSHL will be updated to capture the risk evaluation.

Risk Control

Where the initial risk evaluation is deemed unacceptable, further risk controls are required. MI manages AmDTx risk in accordance with the Risk Management Strategy.

Details of the risk control measure and evidence of effective implementation are captured in the CSHL.

Deployment and Ongoing Maintenance

To support clinical safety activities undertaken during any deployment phases of AmDTx or other programme of work, the following documentation will be required to form a part of the overall approval process:

- MSURF - Making Sense of User Feedback
- Psychobiometric Outputs

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 of the staff identified in the organisation chart, shall be sufficiently competent for the roles and task which they are asked to undertake. Where an individual does not have sufficient experience or knowledge then that person shall be monitored, and his/her 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:

- Making a valid judgement on the safety tasks, activities and techniques required for a given Health Software 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 to 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.

Training

As part of the employment process and thereafter through the appraisal scheme, clinical safety personnel will undergo suitable training to develop, maintain or enhance their competency level. Such training can comprise:

- ‘on the job’ training conducted under supervision
- Internal training courses
- Approved external training courses.

Completion of any safety training shall be recorded by the individual on the annual appraisal form.

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 Team and third-party suppliers.

Internal Safety Audits

MI undertakes regular internal safety audits to ensure that all products, including AmDTx, are compliant with this Clinical Risk Management System.