Clinical Risk Management Plan

Sonera Platform

The Clinical Risk Management Plan (CRMP) defines the processes by which sonera and Sonera Platform manage clinical risk in accordance with the Clinical Risk Management Standard DCB0129.

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Clinical Risk Management Plan

The purpose of this document is to define the processes by which sonera and Sonera Platform manage clinical risk in accordance with the Clinical Risk Management Standard DCB0129.

Introduction

This document is intended to be read by those who are involved in the management of clinical risk within the Clinical Risk Management Lead, Product Manager and Sonera Platform Executive. References to "we" or "our" in this document refer to the Clinical Risk Management Lead, Product Manager and Sonera Platform Executive.

Purpose

The purpose of this document is to define the implementation of our Clinical Safety Management System (CSMS) in accordance with the requirements of the Clinical Risk Management Standard DCB0129 and DCB0160 and DCB0160 Addendum. It ensures that all staff involved with the management of clinical risk are aware of their roles and responsibilities and that clinical risk is managed in accordance with our Clinical Risk Management Policy and Clinical Risk Management Standard Operating Procedure.

The CRMP identifies the roles and responsibilities, the processes and activities required to manage clinical risk in accordance with our Clinical Risk Management Standard Operating Procedure.

The CRMP identifies the hazards to patients and users of our products and services and describes the processes we use to manage the clinical risk associated with our products and services.

The CRMP also describes the clinical safety competency and training, as well as the post-deployment monitoring and change management processes.

Background to clinical safety standards and requirements

The Clinical Risk Management Standard DCB0129 and the Clinical Risk Management Standard DCB0160 are NHS standards for clinical safety in health IT systems. The standards are mandatory for those who are manufacturers of health IT systems.

Abbreviations and Definitions

CSMS	Clinical Safety Management System
DCB	Digital Clinical Safety Standard
HSCN	Health and Social Care Network

Sonera Clinical Risk Management Organisation in the Manufacture of Health IT Systems

Sonera is a small company with management responsibility for development of health IT systems. Sonera is a limited company with a Board of Directors. The Board of Directors is responsible for the governance of the company and for ensuring that the company has the resources it needs to operate and to achieve its strategic objectives. It does not have direct responsibility for clinical risk management.

The Clinical Risk Management Lead is responsible for the management of clinical risk in the manufacture of health IT systems. The Clinical Risk Management Lead is a member of the Board of Directors and has direct access to the Board of Directors. The Clinical Risk Management Lead is responsible for the management of clinical risk in the manufacture of health IT systems. The Clinical Risk Management Lead is responsible for the management of clinical risk in the manufacture of health IT systems. The Clinical Risk Management Lead is responsible for the management of clinical risk in the manufacture of health IT systems.

Scope

The Clinical Risk Management Lead is responsible for the management of clinical risk in the manufacture of health IT systems.