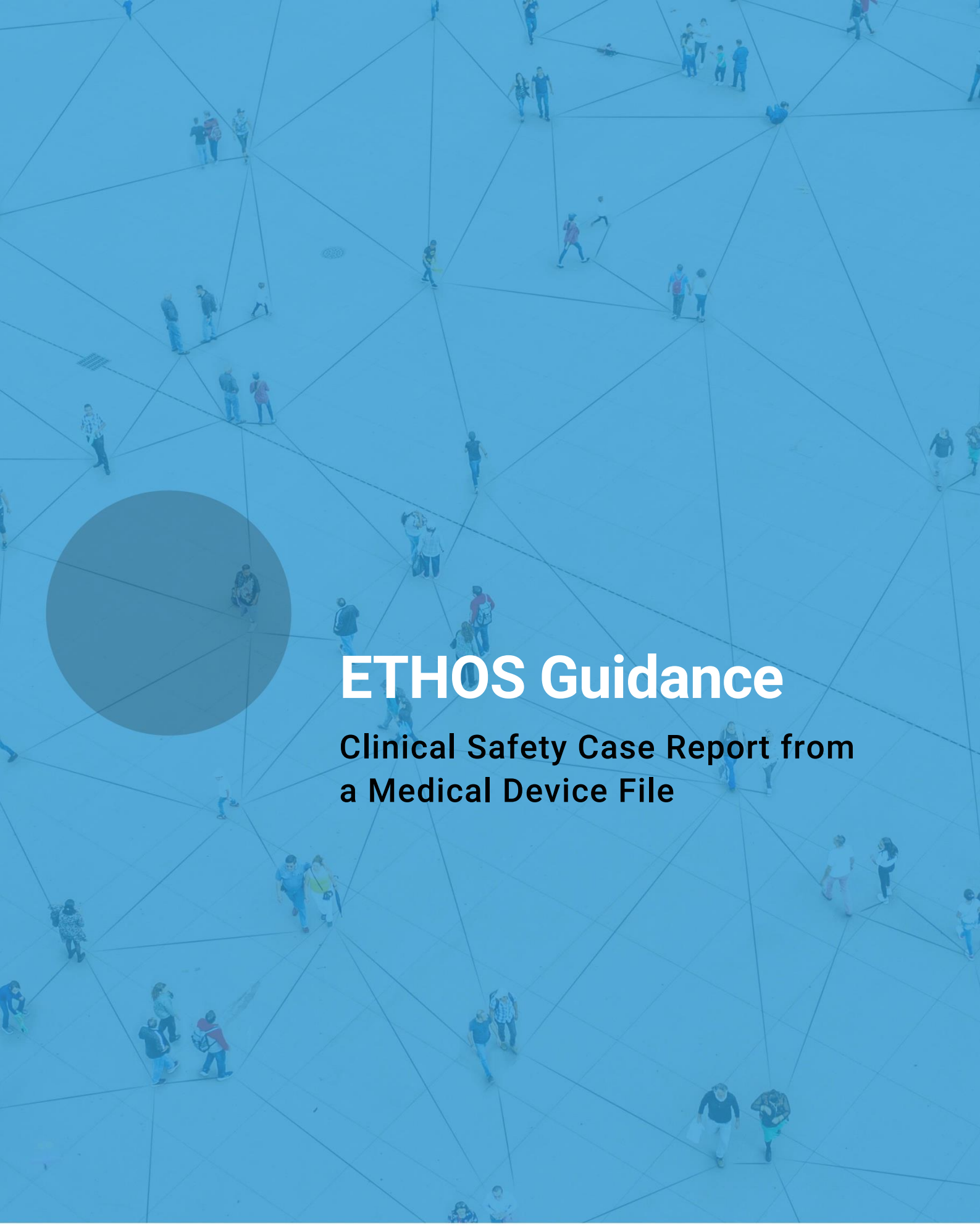

ETHOS Guidance

Clinical Safety Case Report from a Medical Device File

ETHOS

ETHOS Guidance

This guidance is aimed at providing a foundational understanding of clinical safety from the perspective of a manufacturer of a medical device.

The applicability of this guidance is for software as a medical device manufacturer. For further information please see guidance from the original sponsors of DCB 0129 – NHS Digital Background - NHS England.

The Clinical Safety standard is provided below and has been used to extract the requirements we are mapping from and to:

DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems

About this information standard

This standard provides a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those organisations that are responsible for the development and maintenance of Health IT Systems for use within the health and care environment.

The standard includes implementation guidance and is supported by the related standard for the application of clinical risk management in the deployment and use of Health IT Systems - DCB0160.

This information standard is published under section 250 of the Health and Social Care Act 2012. An Information Standards Notice (see below) provides an overview of scope and implementation timescales, and the other documents provide further detail for those who have to implement the information standard.

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DCB 0129 & Requirement 3.5 - clinical safety case report (pg. 28 & 29 DCB 0129)

3.5.1	The Manufacturer MUST produce a Clinical Safety Case Report at each lifecycle phase defined in the Clinical Risk Management Plan.
3.5.2	A Clinical Safety Officer MUST approve each Clinical Safety Case Report.
3.5.3	The Manufacturer MUST make available each Clinical Safety Case Report to a receiving organisation, which may be a Health Organisation or another Manufacturer.

The Clinical Safety Case Report is the primary vehicle for presenting a statement of the clinical safety of the Health IT System. It therefore needs to be a readable document rather than simply a listing of the Clinical Safety Case or the content of the Clinical Risk Management File.

It needs to provide the reader with:

- a summary of all the relevant knowledge that has been acquired relating to the clinical risks associated with the Health IT System at that point in the lifecycle
- a clear and concise record of the process that has been applied to determine the clinical safety of the Health IT System
- a summary of the outcomes of the assessment procedures applied • a clear listing of any residual clinical risks that have been identified and the related operational constraints and limitations that are applicable
- a clear listing of any hazards and associated clinical risks that have been transferred, together with any declared risk control measures, that are to be addressed as part of the Health Organisation clinical risk management process
- a listing of outstanding test issues / defects associated with the Health IT System which may have a clinical safety impact.

The structure of a Clinical Safety Case Report will reflect the organisation of the underlying Clinical Safety Case, which in turn will be influenced by the requirements of this standard. An example structure is provided in Table 6 but should not be considered to be prescriptive or definitive.

The Manufacturer's Clinical Safety Case Reports must be made available to the deploying Health Organisation. This deliverable is a key input into the Health Organisations clinical risk management activities in support of compliance with DCB0160.

Where required and within the framework of any contract terms that exist between a Manufacturer and a Health Organisation, the Manufacturer needs to make available to the Health Organisation any documentation or evidence that is referenced within a Clinical Safety Case Report or which supports the underlying Clinical Safety Case.

It is strongly recommended that the Manufacturer proactively works in close collaboration with Health Organisations following delivery in order to ensure safe and effective deployment of the Health IT System. Such relationships will minimise the likelihood of unanticipated issues occurring and will ensure that any risk controls that the Manufacturer is dependent on the Health Organisation to implement are communicated across organisational boundaries.

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Clinical Safety Case Report Contents (as per DCB 0129)

1. Introduction
   Purpose of the Clinical Safety Case Report and phase of lifecycle it relates to.
2. 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.
3. 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.
4. 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.
5. Clinical Risk Evaluation
   Evaluation of initial level of risk of each identified hazard using pre-defined criteria.
6. Clinical Risk Control
   Identification, justification, implementation, and verification of adequate risk controls; residual clinical risk evaluation and completion of controls.
7. Hazard Log Presentation of associated Hazard Log.
8. Test Issues Summary of any outstanding test issues and the impact on clinical safety.
9. 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.
10. Quality Assurance and Document Approval Evidence of appropriate quality, review, and approval regimes.
11. Configuration Control / Management Evidence of appropriate configuration control being used.

The contents and supporting evidence from the manufacturer's Medical Device File can be extracted into the clinical safety case report. It is advised that in order to reduce the overall effort of documentation and improve the effort of compliance:

- a balance of summary statements, accurate document referencing and the offer to share actual evidential documents from the medical device file, subject to approval, is provided.

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The Hazard Log

Risk management evidence should be included in full, unless commercially sensitive or IP related information is contained within the original risk file / documentation. The option would be to share in full, subject to a legally binding agreement or to distil the relevant risk file into a hazard log and summarise any secure information to remove any sensitive details.

Note – it is important that in the event that sensitive information is redacted that provides contribution to the control and mitigation of risk, further information must be documented as an alternative summary of controls.

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Creating the clinical safety case report

To complete the task, we must understand the basics of the medical device file (Ref – ETHOS Guidance – Medical Device File Structure). This is the body of evidence in which medical device products are certified from. We then need to examine each area of the medical device file and cross reference to the required sections of a clinical safety case report.

At this stage we can simply align documentation ready for summarising, referencing and further assessment on completion. A checklist of MDF vs CSCR is provided in table 1.

Final assessment and completion

As the clinical safety case report is provided to those health organisations implementing and using the product, it is important that the CSCR provides the clarity necessary for further use – i.e., DCB 0160. Although not a mandatory requirement, DCB 0129 does suggest collaboration in this regard helps to improve digital clinical safety assurance activities and customer relationships as a by-product.

Summary CSO statement

The manufacturer may have their own CSO. If not and this function is subcontracted, care must be taken as to the summary provided and claim of compliance to DCB 0129 that is made. If the manufacturer evidence is clear, then there should be limited cause for concern in this regard. It is recommended that the CSO summary statement provided follows a summary statement from the manufacturer and named regulatory, product or quality lead, including any medical or clinical representative.

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Table 1 MDF - CSCR – HL checklist

Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
Description of the device	Manufacturer Details - Name and address of the 'manufacturer' within the meaning of the Directive(s), including representative (if applicable)	2 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.	
	Brief description of the device(s) – principles of operation, description of accessories, variants/configurations	2 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.	
	Intended use description / intended purpose – conditions to be treated / diagnosed, indications / contra-indications, warnings	2 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.	

Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
	Product Description - Identification of the device(s) covered by the 'summary documentation' Description of products and variants Marketing materials (including photos)	2 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.	
	Product Specification - Identification of technical standards with which compliance is claimed	2 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.	Design Control

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Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
Device specification	User requirements – User Interface Specification, user scenarios		Design Control
	Regulatory requirements - classification rationale, risk class, domain specific & organisational requirements	3 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.	Risk Matrices, risk scoring, business process control
	Software Development Plan – process, methods & tools		Design Control
	Software Requirements Specification & Analysis		Design Control

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Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
	Software Architectural Design (including Software Detailed Design) – [if applicable]	2 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.	Design Control
	List of SOUPs		Design Control
Labelling	Labelling (including symbols)		Training Control
	Instructions for use		Training Control

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Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
	Installation and service / maintenance instructions		Training Control
	Training Materials		Training Control
	Packaging & Languages (if applicable)		Training Control
Specifications for its manufacture, packaging, and storage	Production requirements Software Release process Software maintenance plan	10 Quality Assurance and Document Approval Evidence of appropriate quality, review, and approval regimes 11 Configuration Control / Management Evidence of appropriate configuration control being used	Business Process Control

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Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
Proof of conformity, including verification and validation	Clinical Evaluation Report Software Verification Test Report Usability Engineering Plan & Results Risk Management Plan Hazard Log	3 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. 4 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. 5 Clinical Risk Evaluation Evaluation of initial level of risk of each identified hazard using pre-defined criteria. 6 Clinical Risk Control Identification, justification, implementation, and verification of adequate risk controls; residual clinical risk evaluation and completion of controls.	Test Assurance Control Main copy of Hazard Log – noting layout may not be generic NHS style, care must be taken to explain the formatting and style including risk management approach. This musty also be reflected in the CRMP.

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Medical Device File structure		DCB 0129 CSCR Objective / requirement met	Hazard Log
		7 Hazard Log Presentation of associated Hazard Log. 8 Test Issues Summary of any outstanding test issues and the impact on clinical safety.	
Market surveillance	Post Market Surveillance Plan Post Market Clinical Follow-up Plan Post-market data	10 Quality Assurance and Document Approval Evidence of appropriate quality, review, and approval regimes 11 Configuration Control / Management Evidence of appropriate configuration control being used	Business Process Control

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