



Wessex LMC: Digital Clinical Safety and AVT

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Joining the dots across health and care

What will we cover?

Today's session will cover:

1. An introduction to / recap of Digital Clinical Safety (DCS) and DCB0160
2. The system-level approach for DCS developed in the SW Region
3. The SW Region 'AVT System-level Pilot Approach' templates for DCS assurance



What is Digital Clinical Safety? – the law



Health and Social
Care Act 2012

CHAPTER 7

Regulatory bodies have been produced in order to bring understanding within Act and also available support.

CHL79

DCB0129 

Document Name: DCB0129 Specification v4.2.docx

Directorate	Operations and Assurance Services	Project	Clinical Safety
Document Reference	NPfIT-FNT-TO-TOCLISA-1793.06		
Director	Debbie Chinn	Status	Approved
Owner	Stuart Harrison	Version	4.2
Author	Sean White	Version issue date	02.05.2018

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

DCB0160 

Document Name: DCB0160 Specification v3.1.docx

Directorate	Operations and Assurance Services	Project	Clinical Safety
Document Reference	NPfIT-FNT-TO-TOCLISA-1793.05		
Director	Debbie Chinn	Status	Approved
Owner	Stuart Harrison	Version	3.2
Author	Sean White	Version issue date	02.05.2018

Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - Specification

English Health and Care legislation requires that **all** organisations who **manufacture** Health IT systems and those that **deploy and use** Health IT systems undertake the necessary clinical risk activities



What is Digital Clinical Safety? – the standards

DCB0129

Document filename: DCB0129 Specification v4.2.docx
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Clinical Risk Management: its
Application in the Deployment
and Use of Health IT Systems
- Specification

What is Digital Clinical Safety? – the scope

- **In scope:**

- All Digital Health Technologies (DHTs) which could potentially cause harm to patients
- Technical failures, incorrect use, information errors
- Last updated June 2018 (for update soon?)
- Now applies to **all** DHTs, including those with functionality classified as a Medical Device

- **Out of scope:**

- Cyber-security
- Information Governance
- Financial Reporting Systems
- Statistical Reporting Tools

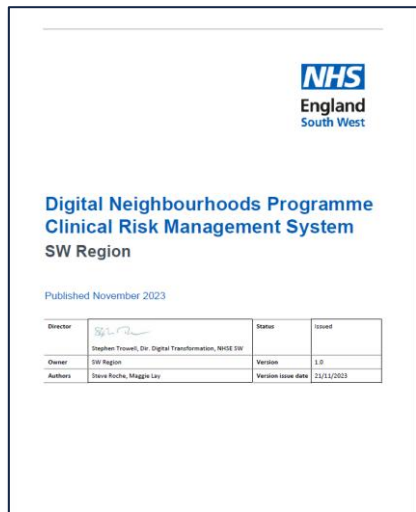
A multiple-organisation challenge - The primary care challenge



- A multi-organisational problem
 - Complex deployments
 - Lack of local CRM knowledge and experience
 - Limited CSO resources locally
 - Capacity constraints
 - Time restrictions
- Not just primary care....
 - ICB level CSO shortage
 - Trust CSO capacity concerns

The system-level solution

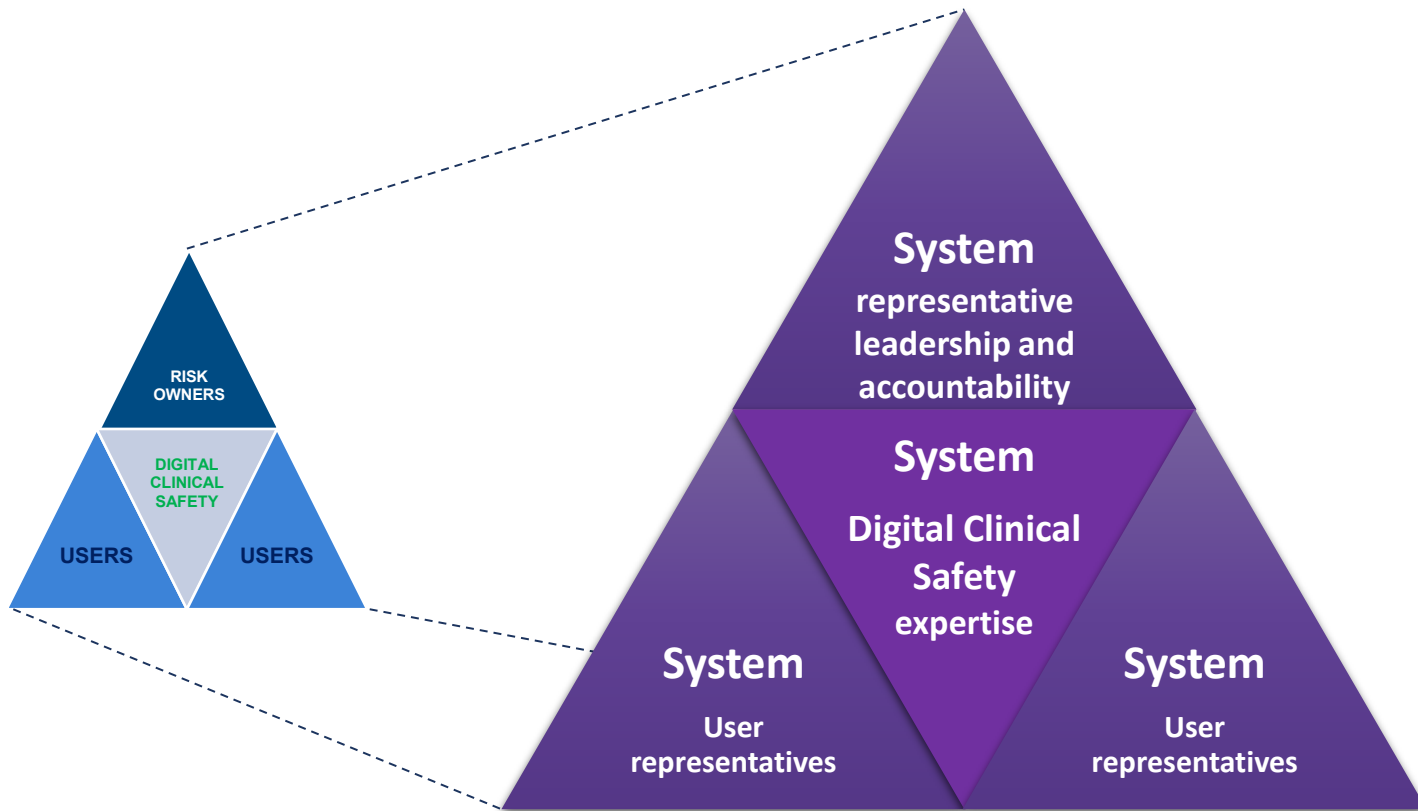
- **A system-level approach to digital clinical safety**
 - Groundbreaking, no previous examples seen of a similar approach
 - A novel regional approach developed to meet identified challenges
 - Scalable and adaptable
 - Centralised support
 - Localised outputs
 - Endorsed and supported by each constituent ICB
- **A cultural shift in digital clinical safety**
 - Improve patient safety across the region
 - Reduce duplication
 - Increase compliance with DCB0160
 - Increase awareness of digital risk
 - Ensure safe deployments



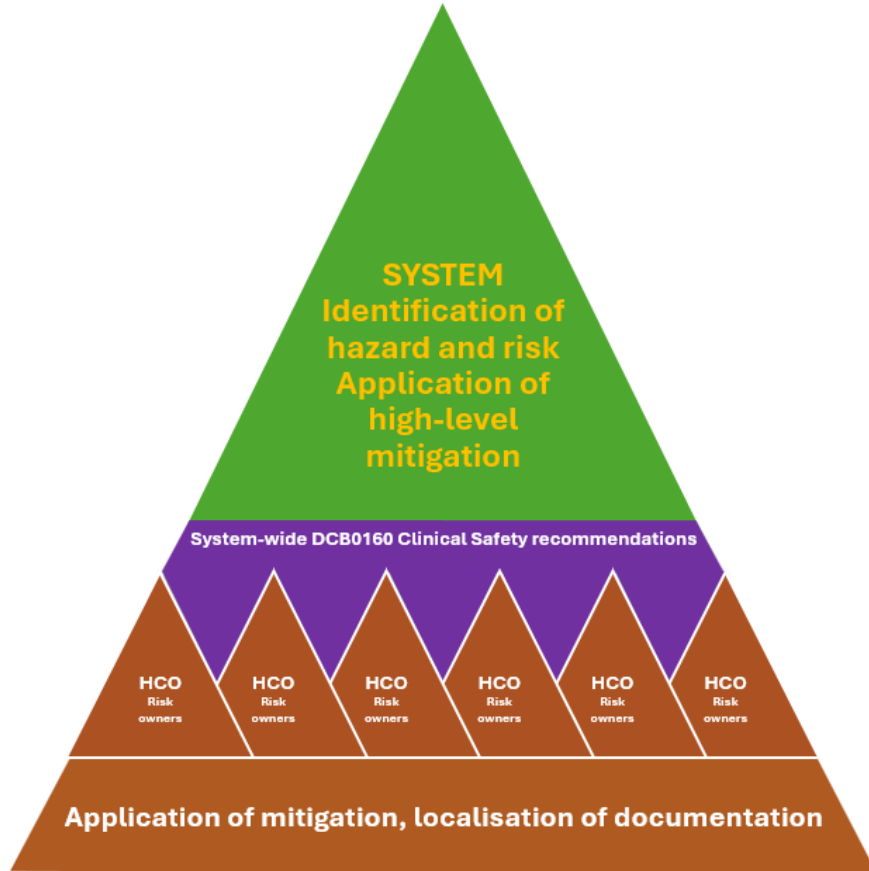
How does it work?



System-level Clinical Risk Management



System-level Clinical Risk Management



System-level hazard workshops completed

Mitigations for unacceptable levels of risk are proposed under the categories of:

- Software changes/configuration
- Education/training/comms
- Business processes/clinical workflow

System-level mitigations:

- applied and tested ahead of residual risk evaluation.

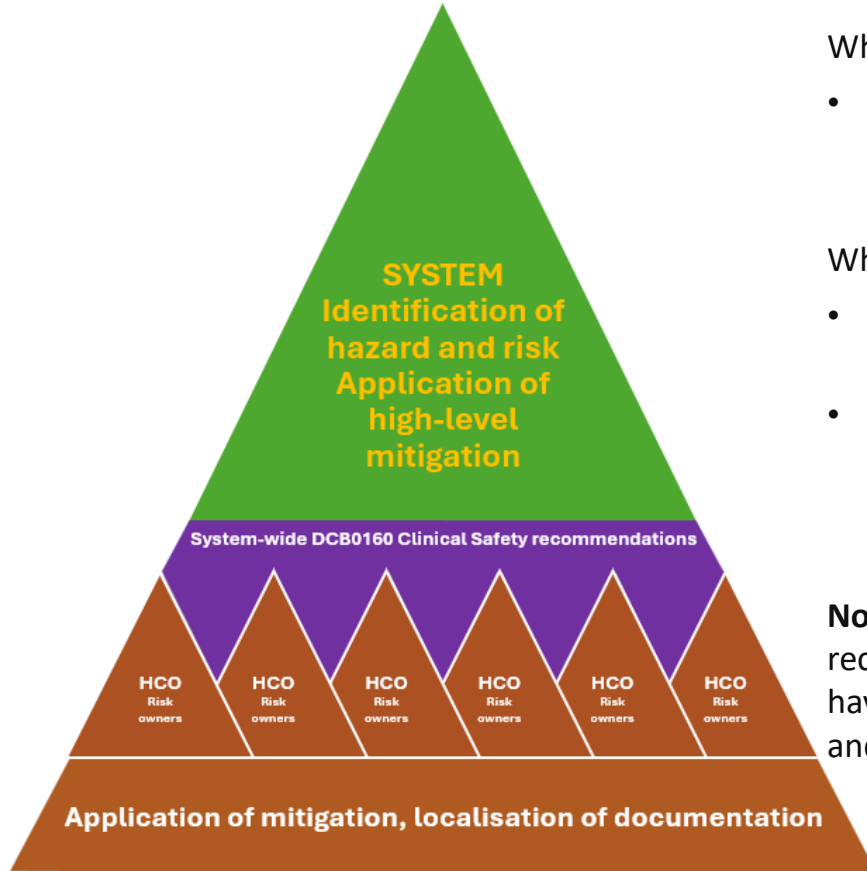
Local-level (HCO) mitigations:

- documented and communicated to the HCOs.

System-level outputs, residual level of risk and recommendations communicated to stakeholders



Local-level Clinical Risk Management



Where **system-level** residual risk is assessed as acceptable:

- Individual Organisations signed up to the CRMS are assured they need do nothing further.

Where mitigations must be applied at a **local, organisational level**:

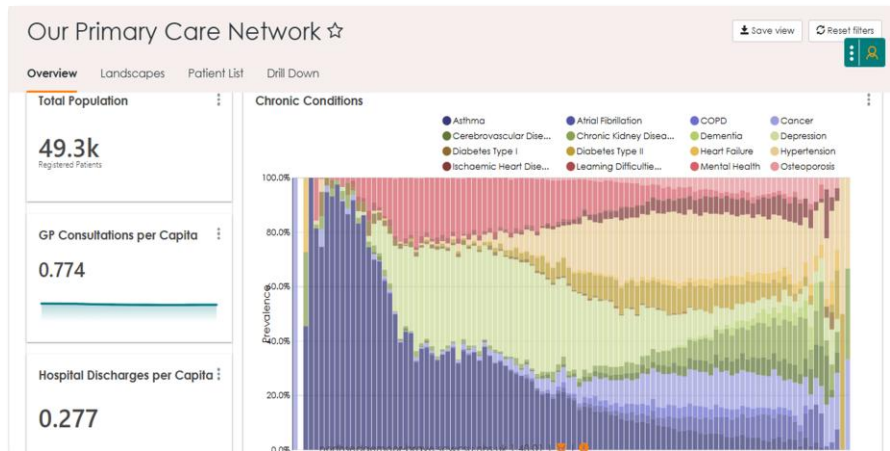
- The programme provides clear recommendations for those local mitigations.
- Once these mitigations have been applied, local risk owners are assured the residual level of risk is acceptable (following local scoring).

Note: where Organisations choose *not* to apply system-level recommendations, or if they choose to deploy technologies which have not been assured by the programme, they remain responsible and accountable for assessing and managing risk.



What have we applied this approach to so far?

Digital Neighbourhoods Programme: Brave AI – a specified product



Commenced July 2023

Ambient Voice Technology – supplier agnostic



Commenced April 2025

Ambient Voice Technology (AVT)



What is Ambient Voice Technology?

Definition: AVT uses AI-powered, large language model (LLM) voice recognition to capture, process, and transform spoken language in real time.

Function in Healthcare:

- Listens passively during clinical interactions.
- Transcribes, structures, and can transfer notes into an electronic health record (EHR).

Benefits:

- Reduces clinician time spent on manual documentation.
- Enhances patient–clinician interaction by removing “screen time” distractions.
- Supports clinical record keeping.

Example: A consultation is recorded by AVT, converted into medical notes, and transferred to the patient’s record.



What does system-level assurance look like for AVT?

NHSE SW Region Clinical Risk Management Pilot Approach for primary care AVT deployments

Every organisation is accountable for the clinical safety of the software it uses. This means that each practice must be able to provide evidence that they have thought about risk and are using the software safely.

This AVT approach is based on the System-level Approach to Clinical Risk Management developed by the South West Region, and approved by the constituent ICBs. It has been produced to support practices and PCNs who wish to ensure that they deploy and use AVT Software safely.

Please remember to automatically enter advice and guidance.

The approach documents the way that organisations to they enter into the approach.

It consists of a set of fields that need to be completed. Fields are not to be communicated with. Four audience is

Overview
Author
Date of review
Version number

The pilot approach

A pilot is a limited-scale, time-bound trial of new healthcare software, conducted in a real-world NHS setting to evaluate performance, safety, usability, and impact prior to wider implementation.

The key features

Controlled Scope
Trials in a small number of practices
Real-world Testing
Assesses function in a real-world setting
Risk Mitigation
Identifies and manages risks
Evaluation Focus
Gathers user feedback
Standards-Based
Aligned with NHS standards

A structured process

The system

If the pilot is successful

An agreement between the pilot and the system

This is covered by the pilot plan

A common software

You are testing

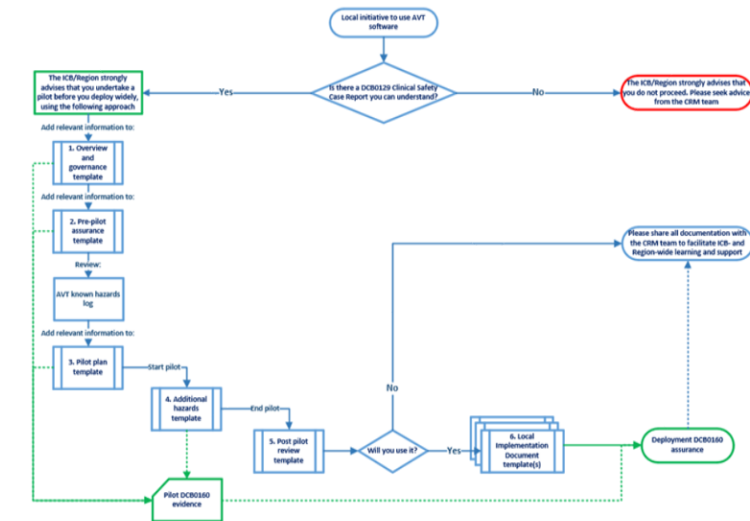
A common purpose

You are going to

The outputs of



Pilot approach for Practices and PCNs seeking to assure and deploy AVT Software



1. Overview and governance template

2. Pre-pilot assurance template

AVT known hazards log

3. Pilot plan template

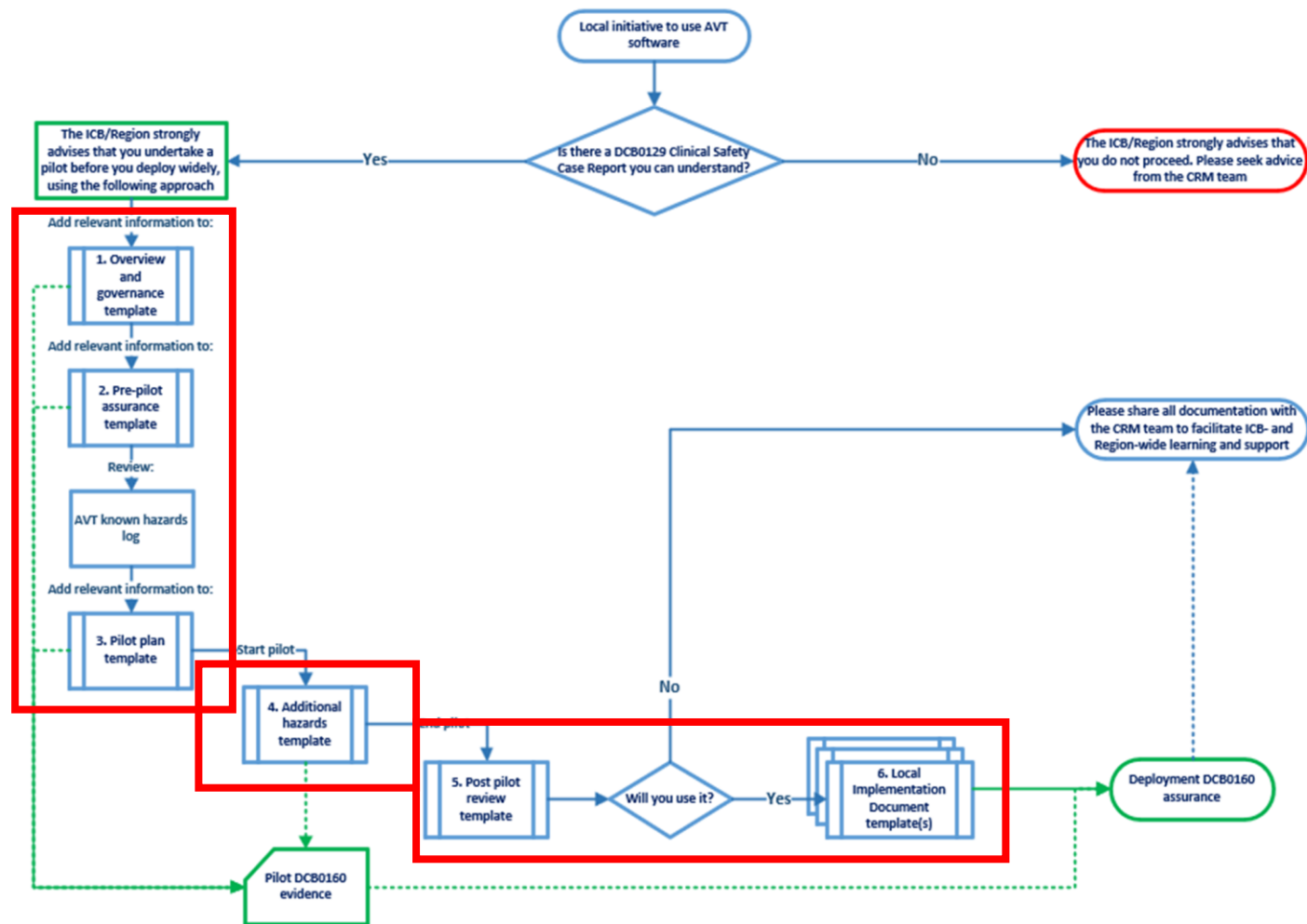
4. Additional hazards template

5. Post pilot review template

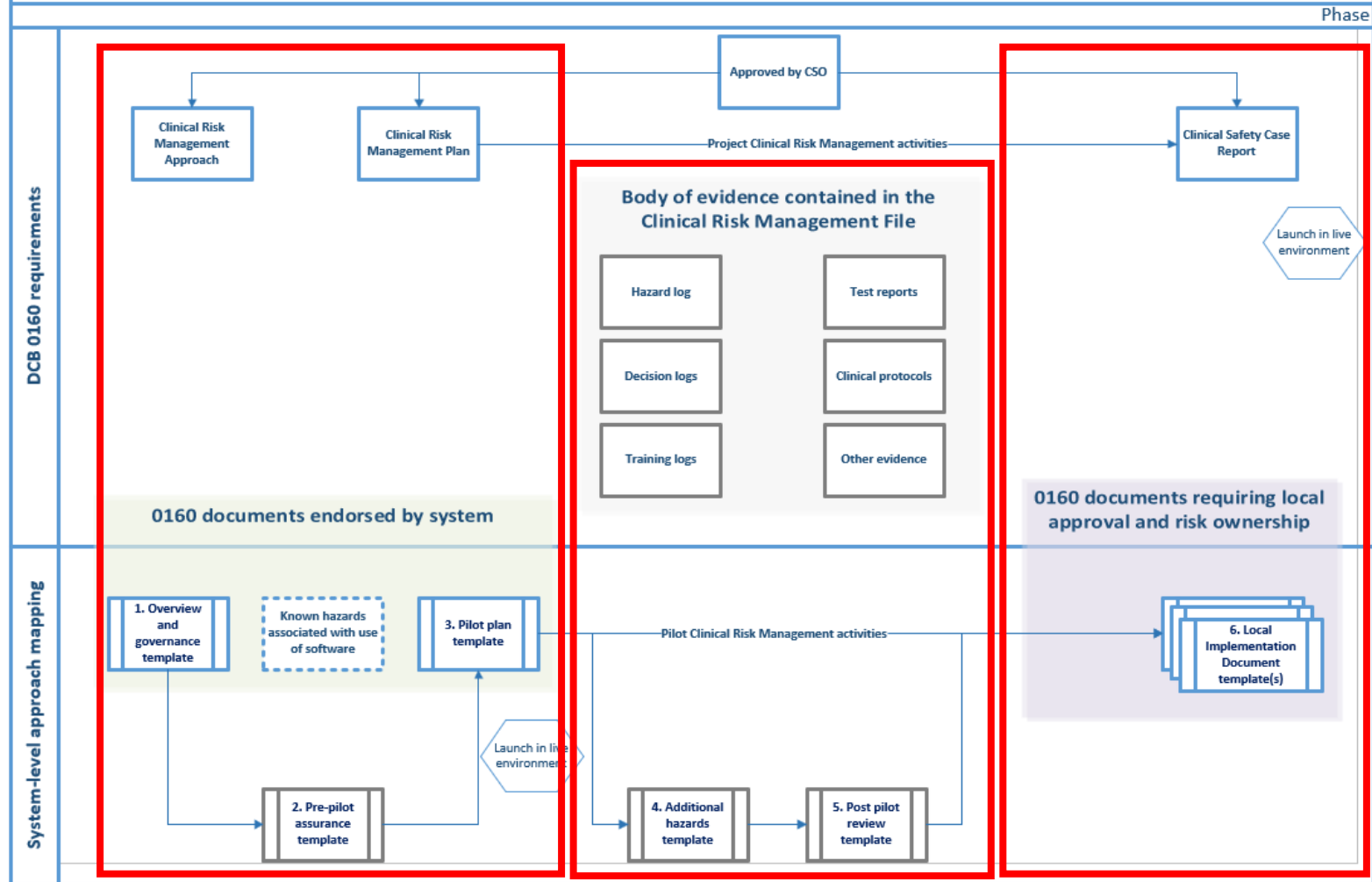
6. Local Implementation Document template(s)



Pilot approach for Practices and PCNs seeking to assure and deploy AVT Software

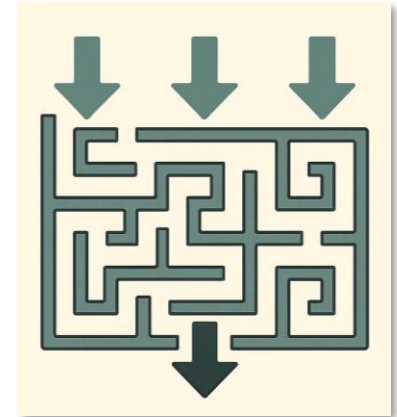
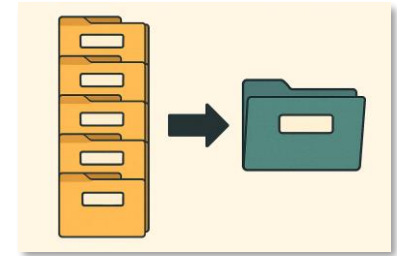


DCB 0160 documents mapped to the system-level pilot approach



Summary and next steps...

- A new, novel solution and approach developed here in the South West Region to address the siloed and repetitive DCB0160 process when deploying:
 - The same digital tool
 - For a similar, specified, clinical use-case
- Fully scalable – from two practices to national deployments
- Adaptable to suit any type of digital deployment
- A cultural shift in digital clinical safety
 - Improve patient safety across a system
 - Reduction in duplication
 - Increase in compliance with DCB0160
 - Increase in awareness of digital risk
 - Ensures safe, at-scale deployments



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Thank you

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