eHealth NSW

A proactive safety approach for design, testing and implementation

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Objectives

- Establish the case for proactive safety management in the context of digital health
- Provide an overview of Digital Health Clinical Safety Management System including
  - the development process
  - its components
  - application considerations

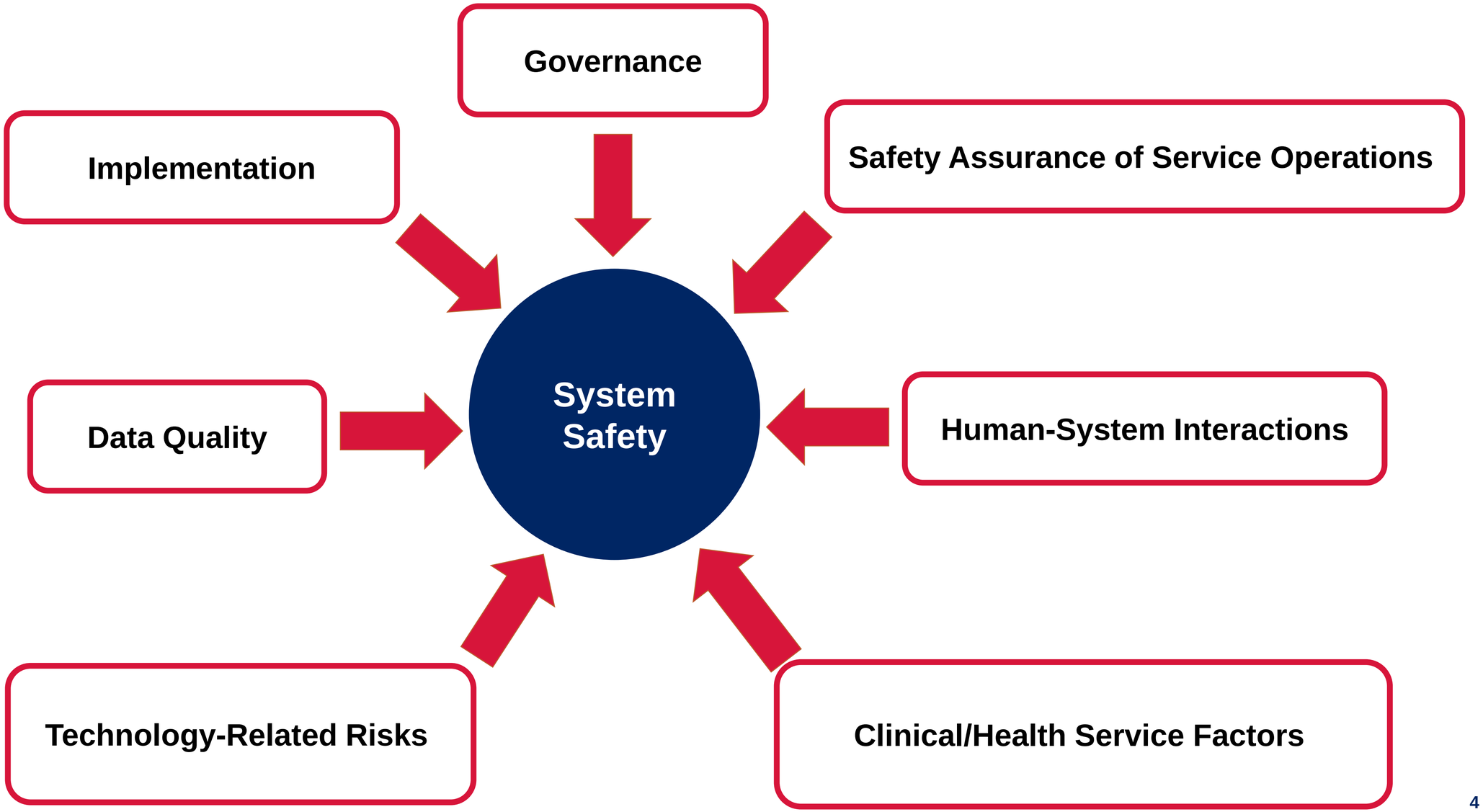
What is a Safety Management System?

A systematic approach to managing safety that applies safety engineering principles in the practice of safety management

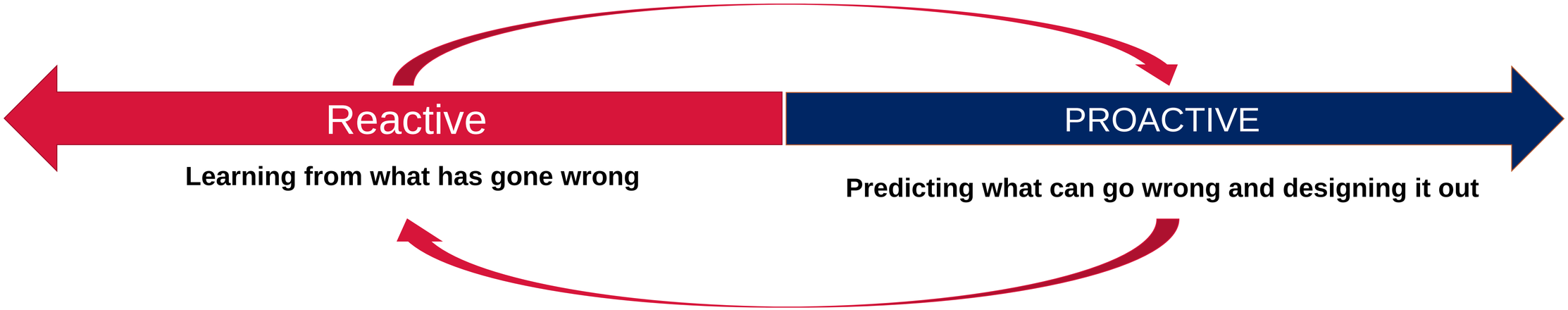
Considers necessary organisational structures, accountabilities, policies and procedures and a range of human factors

Commonly used in other safety critical industries

What Impacts System Safety?



Considerations for development of a safety management system



Mapping of existing safety organisational processes and frameworks, and known relevant standards

Learning from systems safety engineering principles used in other safety critical sectors

Retrospective Safety Thematic Analysis

Governance

- Issues with design governance
- Issues with local local health district/specialty health network governance
- Lack of state-level and district-level governance collaboration
- Vendor safety partnership
- Poor compliance to policy directives
- Fragmented governance related to paper and digital systems

Data Quality

- Incomplete data
- Data not captured
- Poor access to data
- Poor visualisation of data
- Mismatched/incorrect data and data integrity issues

Human-System Interaction

- Poor workflow integration
- Inappropriate design of the digital system
- Work-system interaction relating to the broader ‘system’
- Safe use issues
- Inadequate Clinical Decision Support (CDS

Safety Assurance of Service Operations

- Inadequate testing
- Downtime and uptime management
- Management of ICT-related incidents or defects
- Reliability of service

Implementation

- Inadequate training and education
- Issue with culture
- Inadequate change management
- Issues with readiness

Technology-Related Risk

- System constraints
- Infrastructure and architecture limitations
- System back-end issues
- Lack of/limited/problematic interoperability & interfacing (with devices & other systems)
- Varied technology needs and strategies leading to absence of standardisation
- Privacy and security issues

Clinical/Health Service Factor

- Health system and organisational elements
- Nil state-level consensus
- Clinical Variation

The Clinical Safety Management System (CSMS)

- The CSMS is the **proactive approach** for safety management across the program lifecycle:
  - informed by retrospective thematic analysis of known safety issues (n=382)
  - builds on existing organisational safety management processes
  - informed by systems safety engineering principles.
- Safety will be managed proactively through **prospective approaches to hazard identification and risk management**
- Purpose is to ensure:
  - the ***consistent, robust and proactive*** identification, assessment, management and monitoring of hazards and risks i.e. identifying what can go wrong before it goes wrong then designing it out
  - that design decisions are informed by robust safety analysis.

Components of the CSMS

1. Integrated Safety Governance

- Safety is a shared responsibility
- Most safety issues addressed at working group level
- Minimise escalation outside working group; follow appropriate trigger referrals
- Optimised safety and quality representation
- Align with organisational S&Q processes and frameworks
- Collaborate with key partners

Components of the CSMS

2. Consistent Safety Hazard & Risk Tools

- Prospective hazard identification methods, including Human Factors Integration
- Common and consistent safety terminology
- Hazards log
- CSMS risk matrix
- Risk tolerance thresholds

Hazard Description (Clinical Risk Scenario)	Hazard Cause	Initial Risk	Controls / Mitigations	Residual Risk
Including what clinical risks the hazard might pose	The root cause of the safety hazard	Initial assessment of the risk of the hazard	Actions undertaken or mitigations implemented to manage the risk	Risk level after controls / mitigations have been enacted

		Consequence Rating				
		Catastrophic	Major	Moderate	Minor	Minimal
Likelihood Rating	Almost certain	A	D	J	P	S
	Likely	B	E	K	Q	T
	Possible	C	H	M	R	W
	Unlikely	F	I	N	U	X
	Rare	G	L	O	V	Y

Projected residual risk level	Escalation to Implementation Management Committee and/or Steering Committee	Impact on go-live	Risk management and monitoring
Extreme	Yes	Requires assessment of impact on safe go-live by the Implementation Management Committee and/or Steering Committee. Advice from SQOC and/or SQAG (with assistance from the CLP where appropriate) may be sought to assess criticality and inform go-live decision-making.	Add to Program Risk Register. Other management actions to be determined by the Implementation Management Committee and/or Steering Committee.
High	Yes	Requires assessment of impact on safe go-live by the Implementation Management Committee and/or Steering Committee. Advice from SQOC and/or SQAG (with assistance from the CLP where appropriate) may be sought to assess criticality and inform go-live decision-making.	Add to Program Risk Register. Develop action plan for managing and monitoring the risk. Regular monitoring on a monthly basis at a minimum, with rapid remediation if required sooner.
Medium	No	No notable impact on go-live. Risk has been controlled to a medium level.	Periodic monitoring every 3 months, with remediations implemented as appropriate.
Low	No	No notable impact on go-live. Risk has been adequately controlled to a low level.	Periodic monitoring every 6 months, with remediations implemented as appropriate.

HAZARD

A **HAZARD** is something with the potential to cause harm

CLINICAL RISK

A **Clinical Risk** refers to risks associated with delivering clinical functions resulting from hazards

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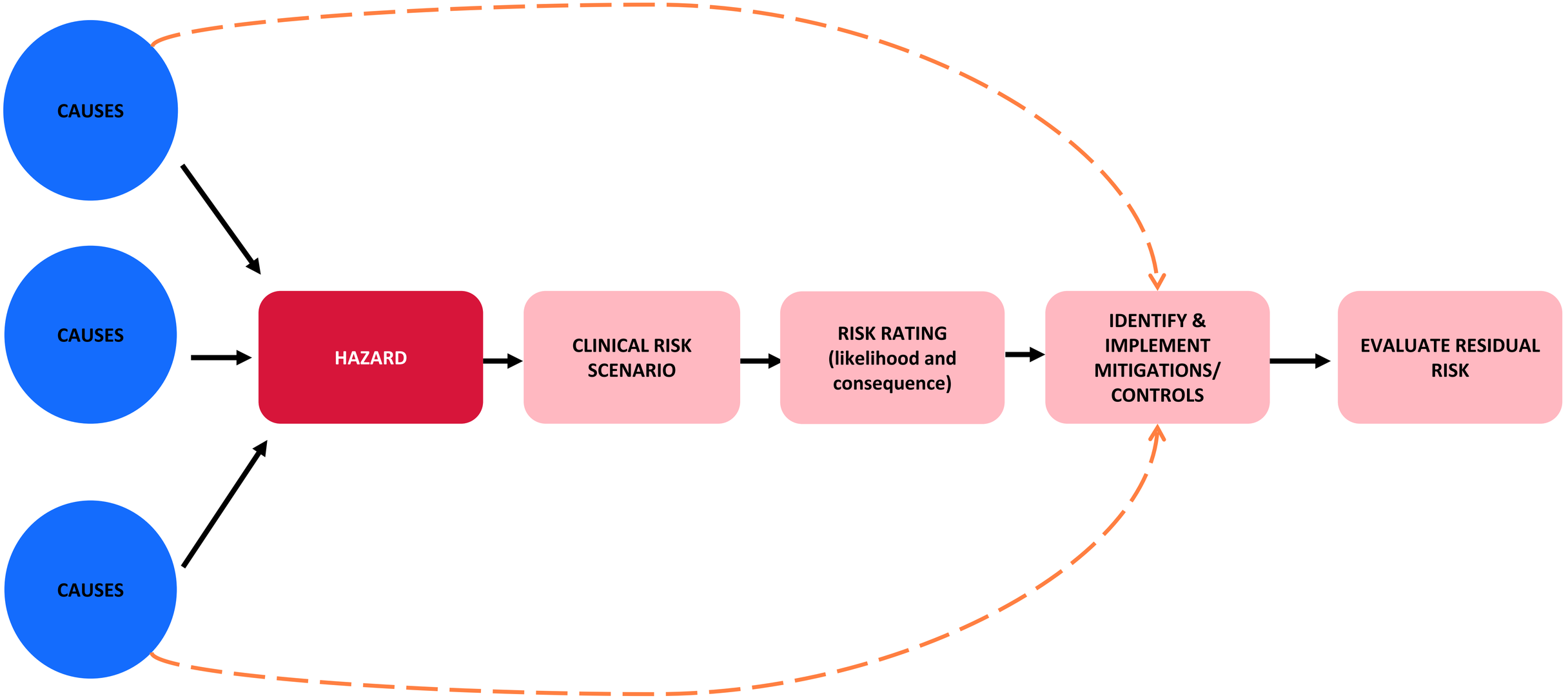
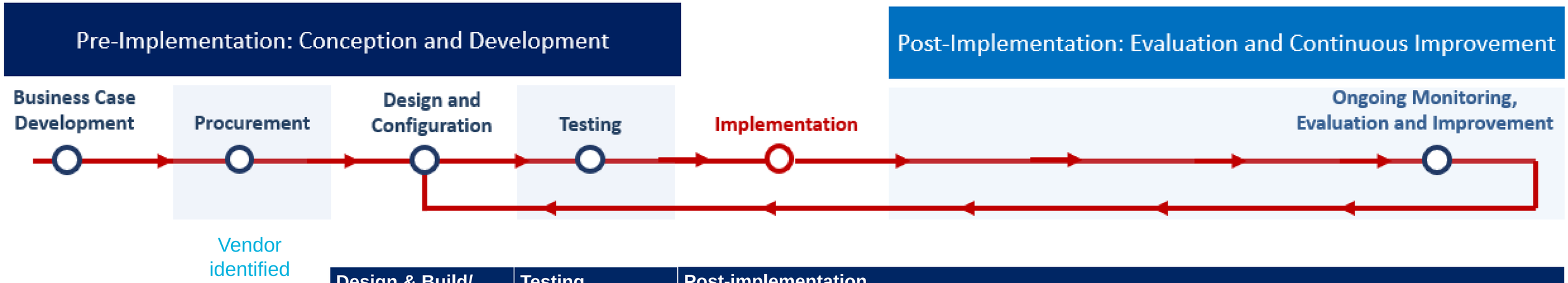
Prospective Hazard identification can lead to the reduction of risk

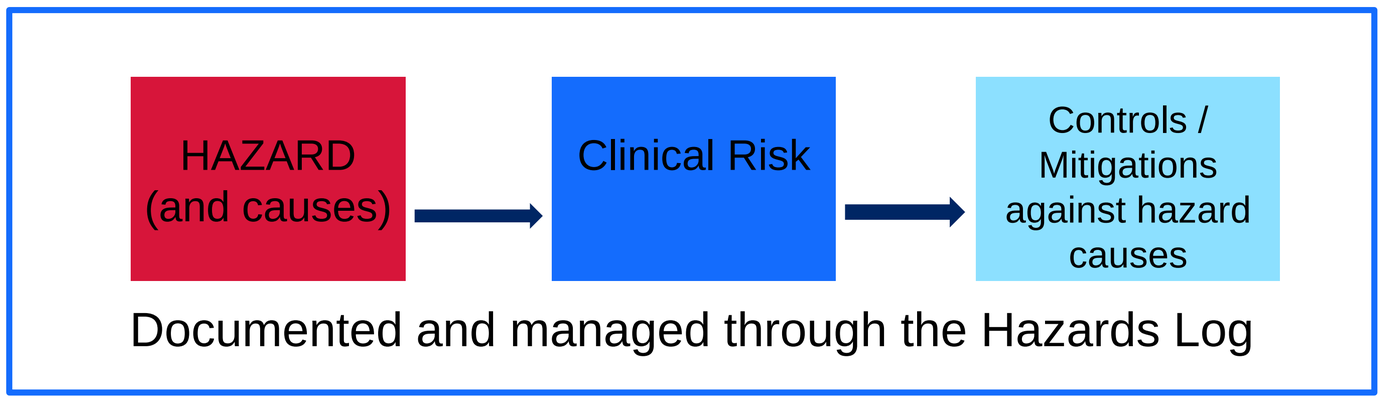


Hazard Identification over the Program Lifecycle



Vendor identified

Design & Build/ Configuration	Testing	Post-implementation
Prospective hazard identification during design: formative and summative phases	Different types of testing will identify defects that need to be managed as hazards as they could introduce clinical risk	Hazards likely to be identified through ongoing evaluation, incident monitoring and other data collection approaches



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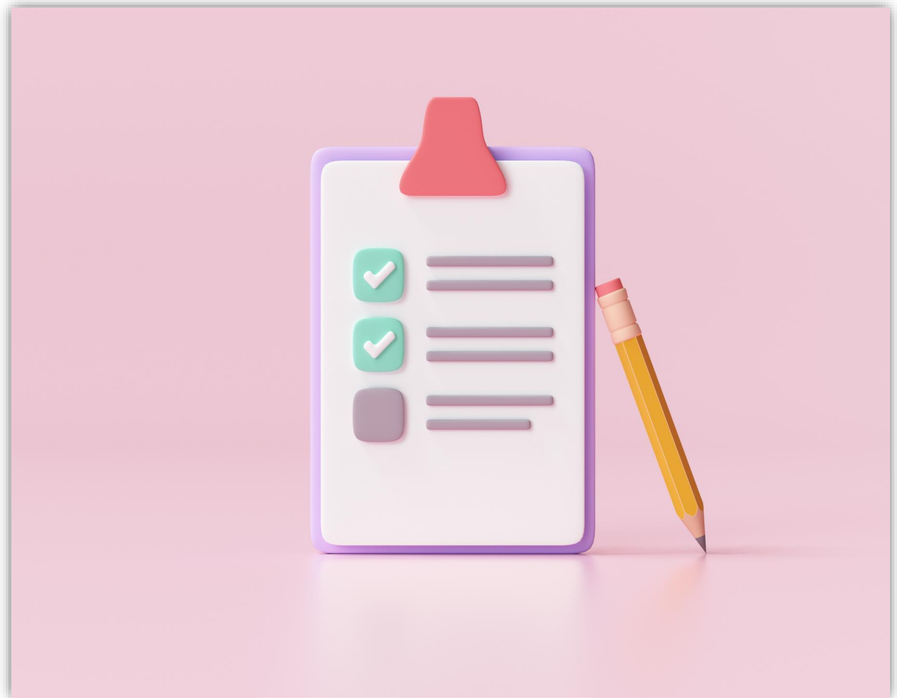
Components of the CSMS

1. Integrated Safety Governance

2. Consistent Safety Hazard & Risk Tools



Documentation

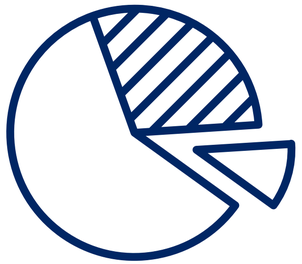
Components of the CSMS

1. Integrated Safety Governance
2. Consistent Safety Hazard & Risk Tools
3. Traceability

Safety centric testing

Operating considerations

Systematic safety assurance focus across the program lifecycle



Aligning with and integrating into the project delivery model, project constraints and other organisational processes

Effective upskilling and onboarding of relevant teams/personnel

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Questions

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