



Digital Health Clinical Safety

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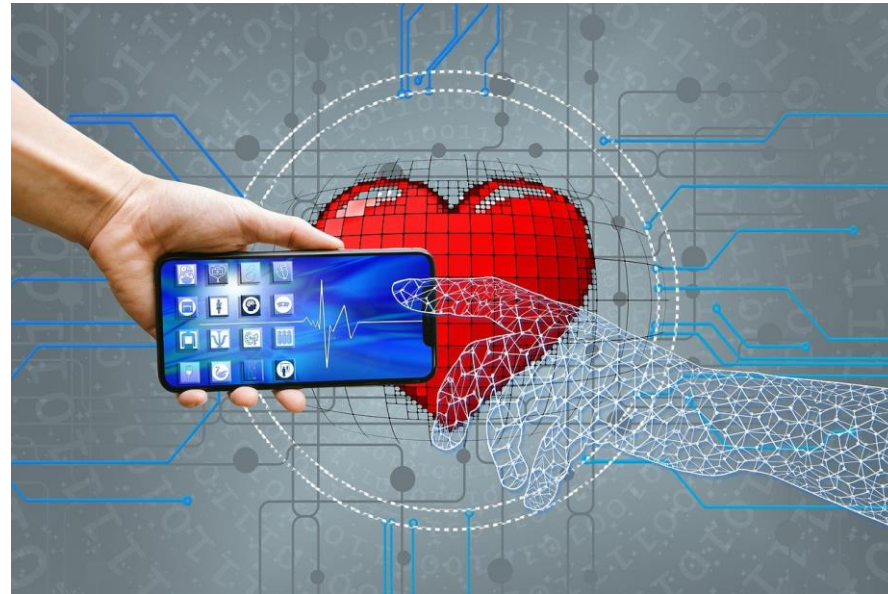


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What is Digital Health Clinical Safety?

Management of all aspects of risk relating to Digital Health including patient safety and service provision.

Planning to Decommissioning.

It's about patient safety.

Apps, Wearables, Digital Systems, AI Algorithms, Clinical Decision Support



Approach is evolving



Learning from other jurisdictions



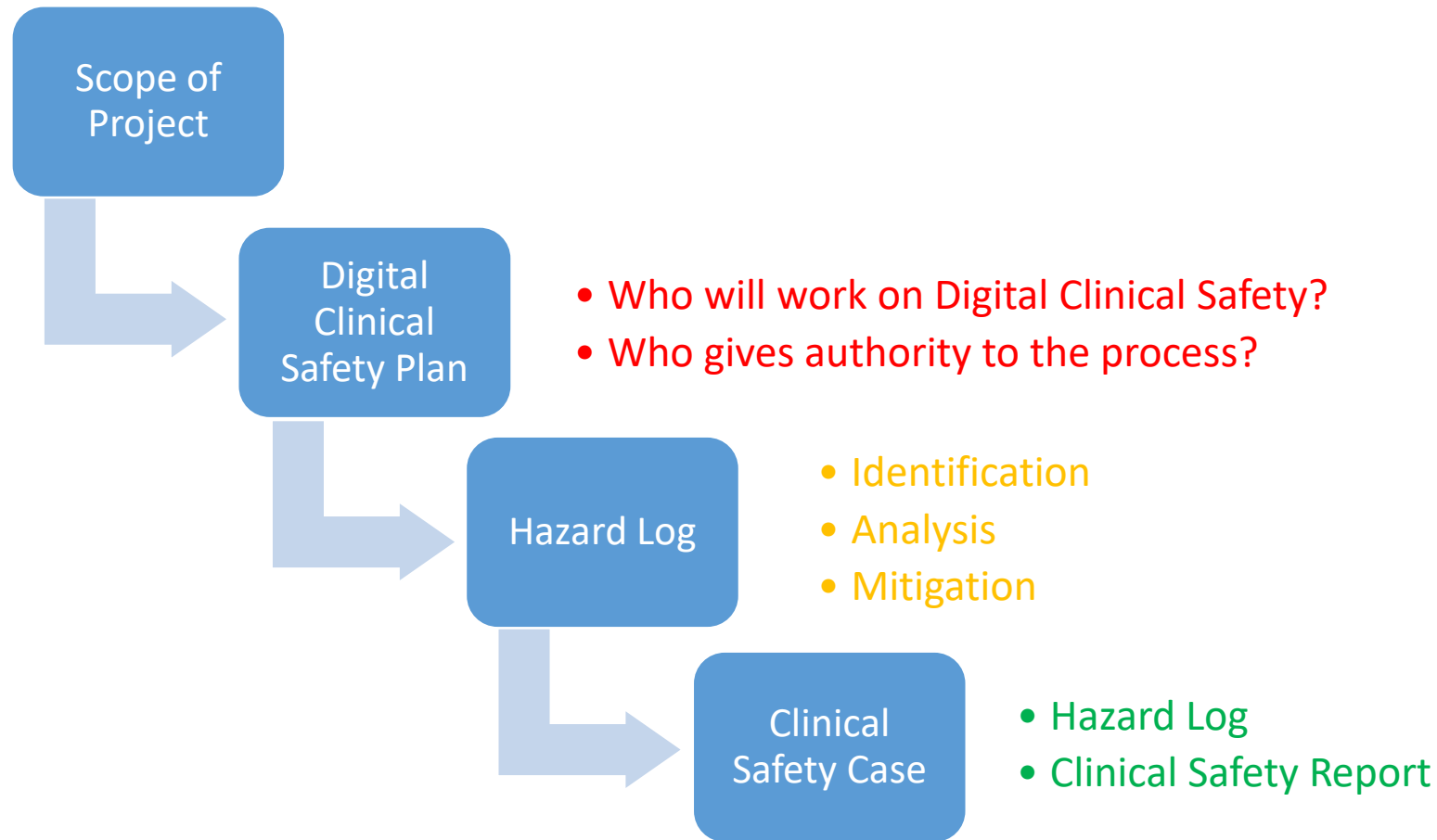
At this stage fine-tuning guidance:

Relevant standards

Hazard Management

Safety Case Development

Digital Clinical Safety Process



Digital Clinical Safety Approach to Virtual Ward Programme

Tender Specifications

Tender Review

Implementation – Hazard Management:

- 107 – 16 open hazards
- 16 are rated 4 or below
- Include 7 for Business Continuity

Living Process

RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Risk Acceptability

Red: Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

Orange (10-12): Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

Orange (6-9): Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. Acceptable when further risk reduction is impractical.

Green (3-5): Tolerable where further risk reduction is impractical.

Green (1-2) Acceptable, no further action required.

Digital Health Clinical Safety Touch-Points



The Art of the Possible

DH is under-pinned by DOH & HSE

Technology is accessible

Drive from patient-facing clinicians

Match health challenges and solutions

People, Process and Technology

Do it safely

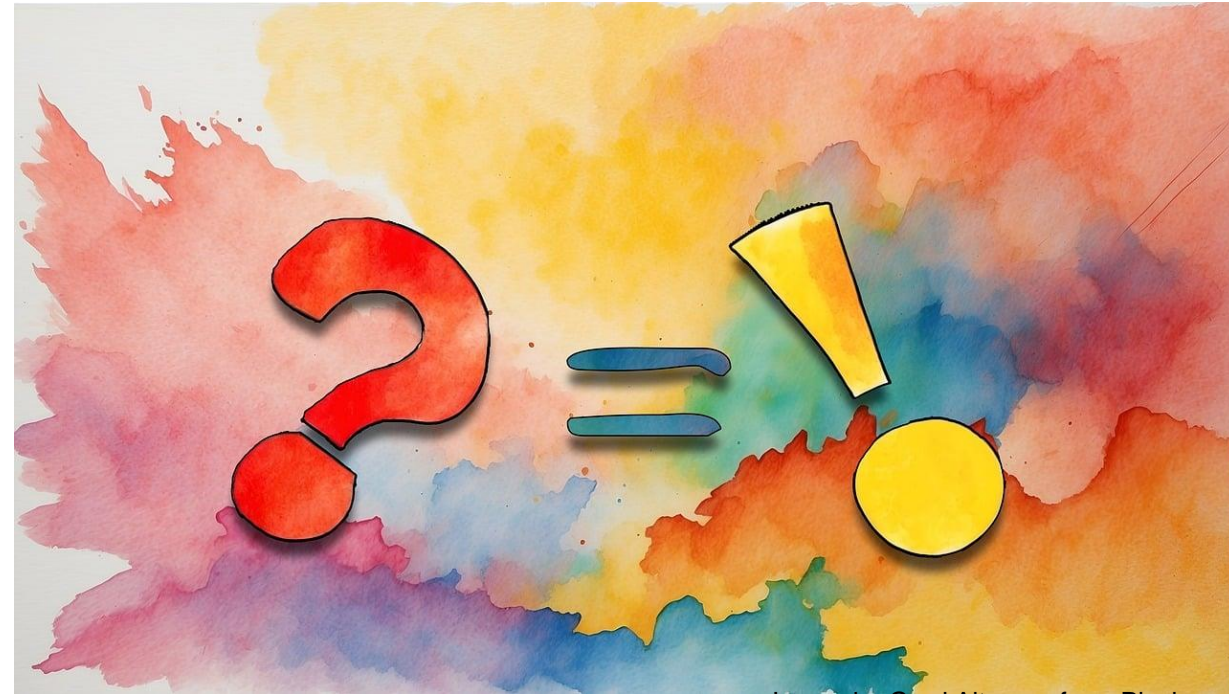


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