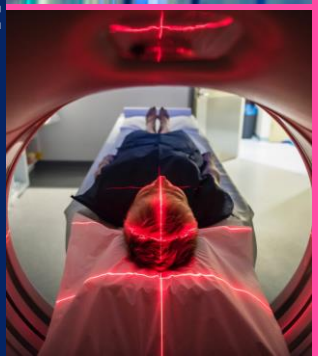
Clinical Risk Management: Beyond Device Failure






Sally Sennitt MBBS, FRCA

30 MAY 2024

Agenda

- **Clinical Risk Management Throughout the Device Lifecycle**
  - **Why do it**
  - **When**
  - **Who to get involved**
  - **How to make it work**
  - **Signs of success**

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- **Clinical Risk Management Throughout the Device Lifecycle**

Why do it

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Why?

‘All’ activities prior to market authorisation….

‘All’ activities during post-market phase…..

Is the Benefit Risk profile/ratio for this device favourable?

ISO 14971:2019 Medical Devices – Application of risk management to medical devices

ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary

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Benefit Risk Ratio

Does the clinical benefit of its use outweigh the risks?
Is the device safe?

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- **Clinical Risk Management Throughout the Device Lifecycle**

When

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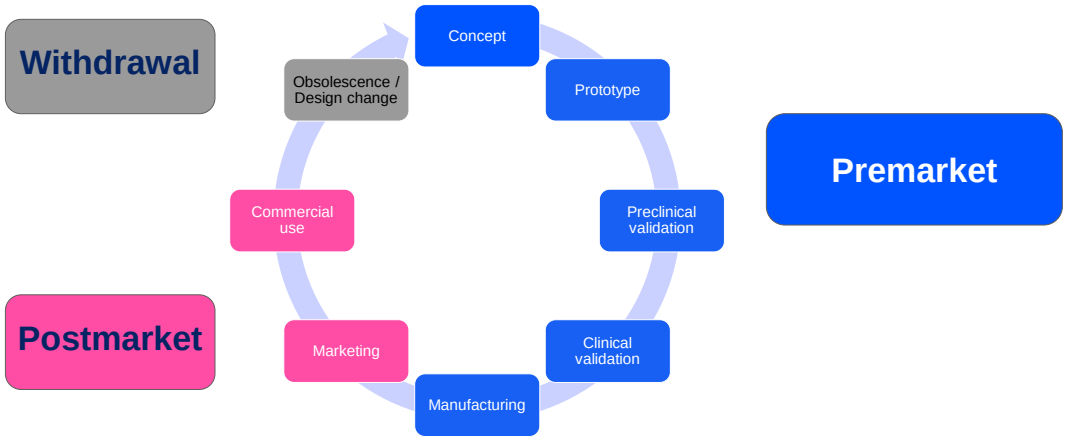
When?



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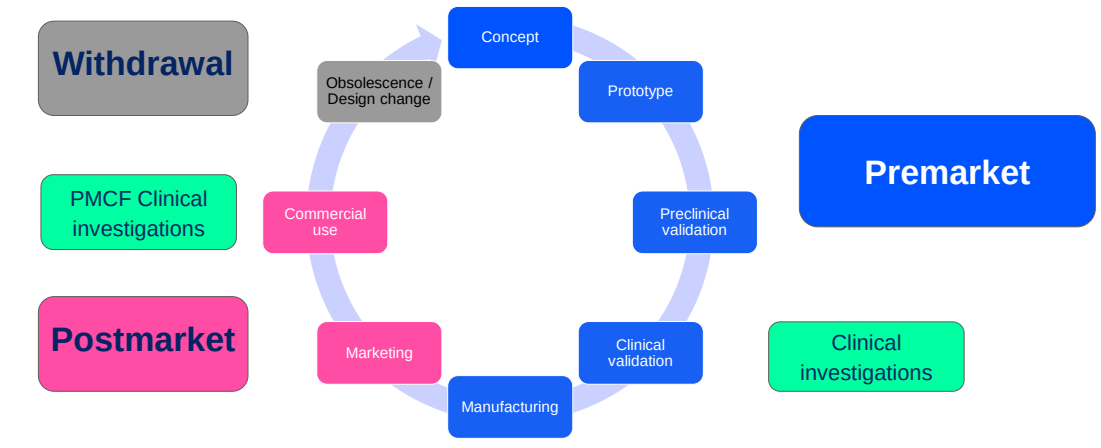
When?



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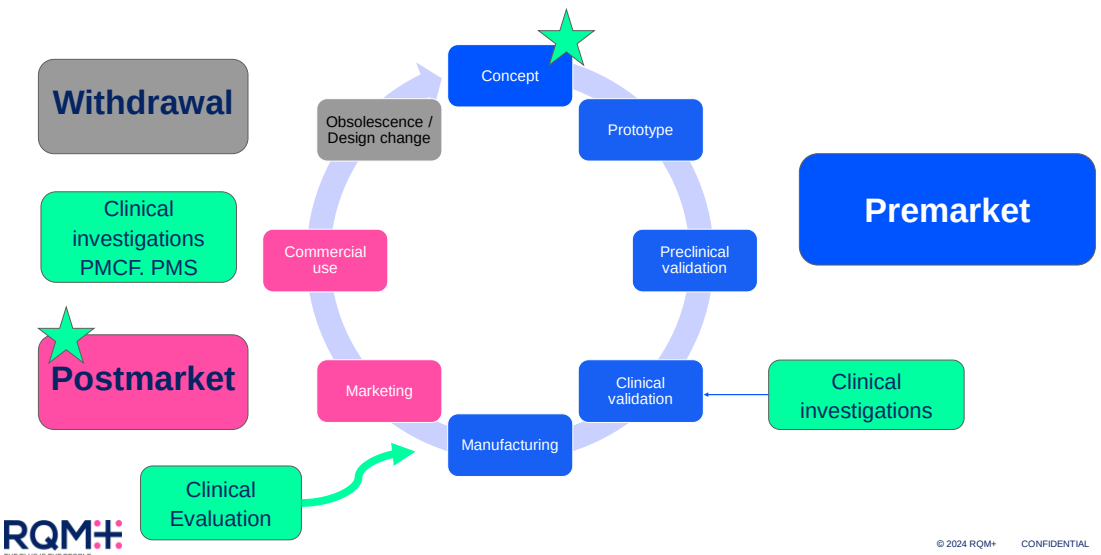
When?



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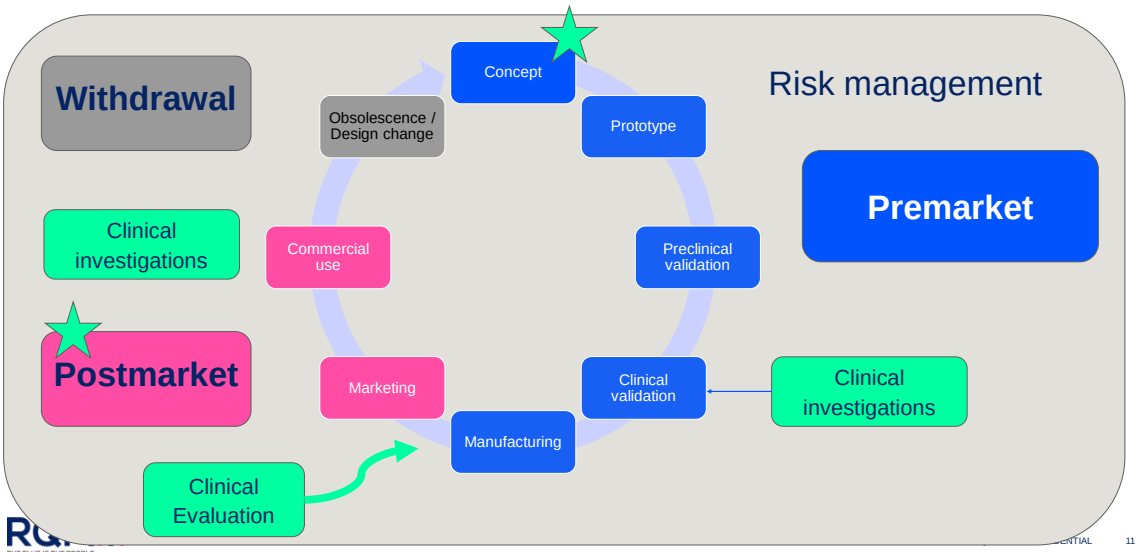
When?



- **Clinical Risk Management Throughout the Device Lifecycle**

Who to get involved

Risk management planning

ISO 14971:2019

Personnel performing risk management shall be knowledgeable and experienced to cover all aspects of the risk management process…

- Design, construction, function
- Intended use
- Regulatory requirements
- Production processes
- Supply chain issues
- Applicable ISO/IEC standards etc.
- Validation
- Risk management process
- Device lifecycle activities (e.g. maintenance, service, complaints)

✗ **One person**

✓ **A multi-disciplinary team of knowledgeable people**

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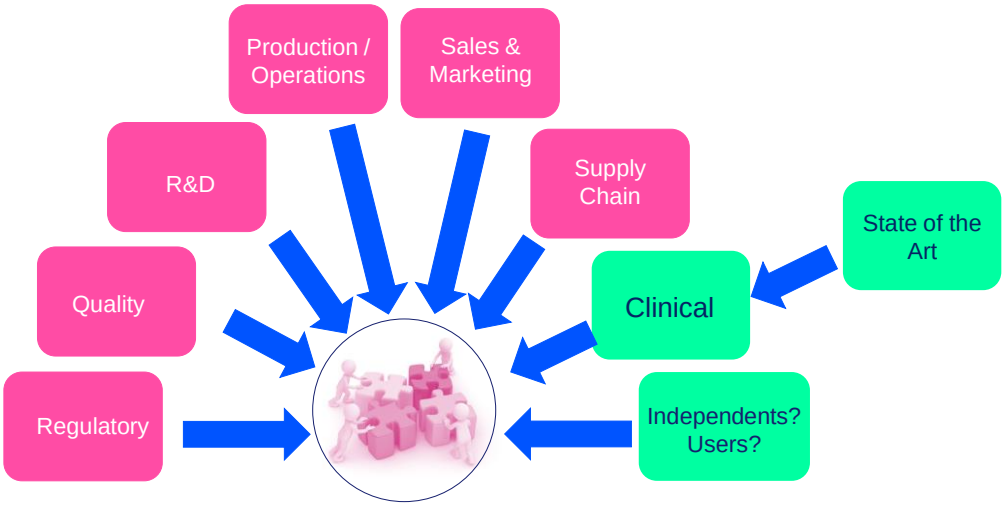
Risk management planning



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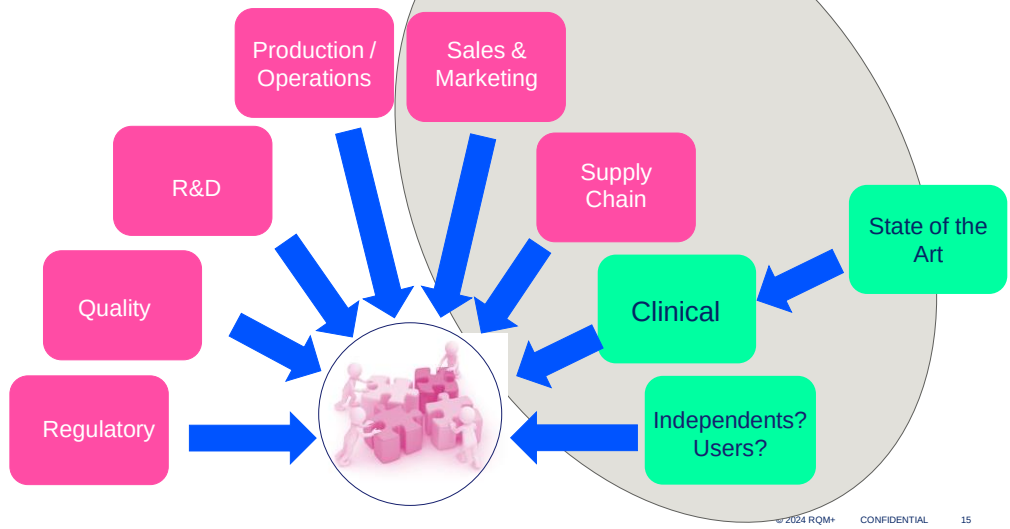
Risk management planning



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- **Clinical Risk Management Throughout the Device Lifecycle**

How to make it work

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How to make it work – Risk identification

- Getting clinicians and *relevant HCPs* involved from the start*
- Use clinicians to ask the right questions and to help find right experts if they don't have the specific expertise required
- Start with a systematic review of the state of the Art (SOTA)
- Comprehensive coverage of processes around device use – implantation procedure, removal & replacement, dressing applications, associate devices and accessories,
- *Start = NPD design concept stage

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How to make it work – Risk identification

- Consider user and patient perspective, different patient groups, indications, disease severity, user environments (home, hospital, field, patient-users, carers etc)
- Foreseeable use and mis-use – breakage, connections, accidental desterilisation, sizing, compatibility, allergies and sensitivities
- Get granular – are all infections the same in terms of significance?

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How to make it work – Risk analysis

- Use RM process to focus in on intended purpose, indications, contraindications, high risk groups requiring additional clinical data
- Ensure risks are traceable to relevant patient / use groups for easy stratification

How to make it work – Risk mitigation

- Use the same team when evaluating mitigations and residual risks
- Keep mitigation proportional ALAP without adversely affecting clinical benefit
- Final list of residual risks is an input to the clinical evaluation process – most will appear in the IFU as warnings / known adverse events – needs to make sense to a Dr.

How to make it work – Risk mitigation

- Clinical team should be encouraged to:
  - Oversee translation of risks to hazards and harms,
  - Take some ownership of the Master Harms List
  - Review relevant parts of risk management reports

- **Clinical Risk Management Throughout the Device Lifecycle**

Signs of success

Thoughts from a risk expert

- Risk is everywhere, safety does not mean ‘risk free’.
- Risk management is quite simple at a basic level.
  - Identify
  - Analyse
  - Evaluate
  - Control
  - Monitor
- To do it well requires:
  - teamwork
  - understanding your device, your stakeholders, your audience
  - effective communication throughout the process

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What does good clinical RM look like?

- Clinical reviewer of CER will recognise the contents, logic and consistent terminology of the input documents:
  - State of the Art review (SOTA)
  - Risk management report
  - List of residual risks
  - CSRs
  - PSUR/ PMSP
  - PMCF Reports

Processes are integrated

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What does good clinical RM look like?

- The CEP will be easy to write/update – benchmarks (including safety) will have been established for each relevant patient population,
- The RM documentation will naturally align with CEP and CER in terms of residual risks,
- CER updates can be confidently made on the strength of the inputs without any retrospective Tech File remediation.

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What does good look like?

I want to congratulate with you, your team and the consultant company, this is the first time I didn't raise a single question during clinical assessment. Please consider that Clinical Oversight process already started and there might be request of clarification from the internal clinician.

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Thank you!

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