



Quality practices in clinical research



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Objectives



- To introduce the importance and the role of quality in a clinical research setting
- To design a quality system which supports the research rather than constrains it
- To ensure the quality of the environment in which the research is performed



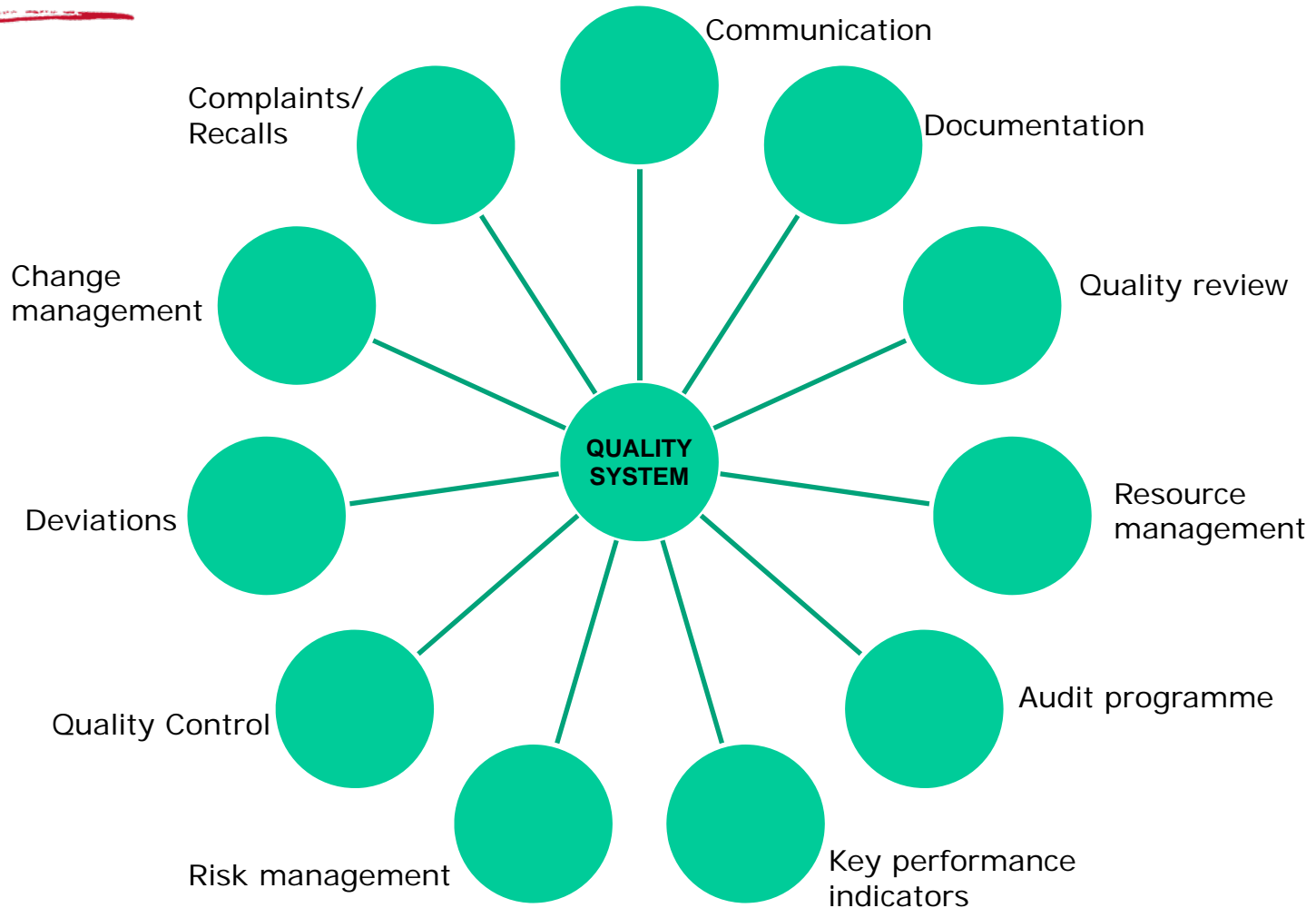
Implementation



- Define what the institution means by 'quality'
- Ensure the institution is committed to implementing quality
- Decide which standard meets your requirements
- Introduce the principles of the standard to the department and ensure that they are tangible



Implementation





An example



- At the MRC the first element of the quality system we are implementing is documentation.
- Documentation – friend or foe?
- Ensuring documentation supports your processes without you drowning in paperwork



Discussion & Conclusions



- Lessons learnt:
 1. Keep the scope of the implementation achievable
 2. Remember the goal is to provide confidence your data are reliable and reproducible
 3. Engage all the affected staff, including any interfacing department
 4. Make sure you provide feedback



Future perspectives



- Certification to Good Clinical Laboratory Practice
- To be able to demonstrate to the international community the quality of the clinical research
- To build on our understanding so that quality becomes part of our everyday activities