Risk overview

1. Risk Identification
   - Identify risks and their causes

2. Risk Assessment
   - Estimate likelihood and impact of risk

3. Risk Management Plan
   - Actions/processes to mitigate risk. Incorporate actions in protocol, Clinical Monitoring Plan, SOPs, safety monitoring plan, staff training

4. Monitoring and Review
   - Implement risk management plans, track risks, monitor residual risk, identify new risk, re-evaluate risk plans

5. Communication and Consultation
   - Document and report risk management effort and outcome

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