

# Integrating Principles of Quality Management into Clinical Research

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## Objectives:

- ▶ Understanding quality in the context of clinical research
- ▶ Overview of key quality principles
- ▶ How to implement components of quality management in clinical research

# Integrating Principles of Quality Management into Clinical Research

## Importance of Quality In Clinical Research

- ▶ **Regulatory Requirements:** Overview of regulatory standards and guidelines (e.g., ICH GCP E6 (R2), TCPS2, Health Canada Part C Division 5)
  - ▶ Institutional policies, departmental SOPs, protocol
- ▶ **Impact on Outcomes:** How quality affects data integrity and participant safety
- ▶ **Definition of Quality:** What does quality mean in the context of clinical research?

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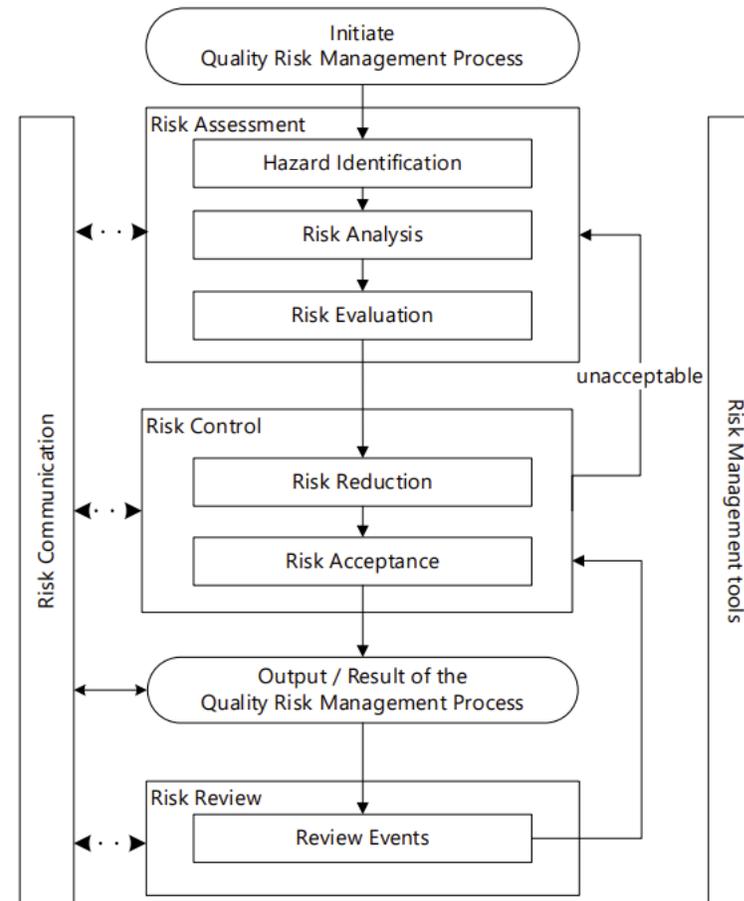
## Key Quality Principles

- ▶ **Consistency:** Ensuring consistent procedures and protocols
- ▶ **Accuracy:** Importance of accurate data collection and reporting
- ▶ **Reliability:** Building reliable and reproducible results
- ▶ **Transparency:** Maintaining transparency in methodologies and reporting
- ▶ **Communication:** Effective communication among team members and stakeholders

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## Implementing Quality Principles

- ▶ **Risk Management:** Identifying and mitigating risks in clinical research – can select the appropriate mitigation tools and strategies



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## Implementing Quality Principles

- ▶ **Risk Management:** Performing risk assessment to identify hazards and evaluation of risks associate with exposure to identified hazards
- ▶ Three fundamental questions:
  - ▶ What might go wrong?
  - ▶ What is the likelihood (probability) it will go wrong?
  - ▶ What are the consequences (severity)

Risk Rating = Likelihood x Severity

Consequence	Extreme	5	10	15	20	25
	Severe	4	8	12	16	20
	Substantial	3	6	9	12	15
	Moderate	2	4	6	8	10
	Slight	1	2	3	4	5
		Very unlikely	Not likely	Likely	Very Likely	Extremely likely

Very high risk  
High risk  
Moderate risk  
Low risk

Likelihood

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## Implementing Quality Principles

- ▶ Standard Operating Procedures (SOPs): Developing and adhering to SOPs

- ▶ Consistency 
- ▶ Accuracy 
- ▶ Reliability 
- ▶ Communication 

**Are there any SOPs that your department or team have recently needed to create?**

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## Implementing Quality Principles

- ▶ **Study Tools and Templates:** Designing templates for data collection and using checklists to ensure all assessments are performed

- ▶ **Consistency** 
- ▶ **Accuracy** 
- ▶ **Reliability** 
- ▶ **Transparency** 

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## Implementing Quality Principles

- ▶ **Identifying protocol deviations:** Capturing protocol deviations and preparing a Corrective Action / Preventive Action plan where applicable.

- ▶ Consistency 
- ▶ Transparency 
- ▶ Communication 

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## Implementing Quality Principles

- ▶ Training and Education: Importance of trained and qualified staff

- ▶ Consistency
- ▶ Accuracy
- ▶ Reliability
- ▶ Transparency

**Any other methods you have implemented to promote quality?**

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**Questions?**

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