A Step-by-Step Guide For Risk Management In Clinical Investigation Process, Medical Devices

Sl. No.	RISK PARAMETERS	RISK MANAGEMENT ACTIVITIES	WHAT ARE YOU DOING AS A SPONSOR?
1.	**Risk identification**	Identify from applicable sources: example - animal studies, design input, market experience, literature data	
		Conduct a preliminary assessment to identify probable sources of risk in the clinical investigation and document them	
2.	**Risk Assessment**	Details analysis and evaluation of risk assessment	
		It should include an objective review of published literature	
		Identify and control risks associated with the clinical investigation processes to ensure ethical and scientific conduct remains credible	
		Risk control measures should be considered at the clinical quality management system level (e.g., SOPs, computerized systems, personnel) and clinical investigation planning and conduct (clinical investigation design, data collection, informed consent process)	
3.	**Risk Estimation**	Risk related to the device and its procedure should be estimated in accordance with ISO 14971	
4.	**Risk Acceptability**	Pre-define risk acceptability thresholds and trigger risk assessment to determine the action needed as thresholds are reached	
		Monitor risk against pre-define risk acceptability thresholds	
5.	**Residual Risks**	For a clinical investigation, residual risks should be identified in the risk analysis.	
		Risks associated with clinical procedures including follow-up be balanced against anticipated benefits to the subjects.	
		Contraindication and warnings of the investigational device	

		If, under any condition, the risk associated is "not at all acceptable" or potentially a threat to the participant, consider terminating clinical ingestion on an immediate basis.	
		Identify the defects and mitigate them. Unless the 'unacceptable' risk is completely eliminated, suspend the clinical investigation.	
6.	**Benefit-risk analysis**	Evaluate the overall residual risk acceptability	
		Clinical investigational plan (including investigation brochure) should include: ● Anticipated clinical benefits Anticipated adverse device effects ● Risk associated with participation in the clinical investigation ● Possible interactions with concomitant medical treatments as considered ● Rationale for the benefit-risk ratio ● Steps that will be taken to control or	
		Informed consent form shall specifically disclose: ● anticipated adverse device effects ● statement of unanticipated risk can occur ● description of inconveniences ● information on financial compensation in case of an unexpected event or outcome	
7.	**Risk management**	Risk management shall be an integral part of the entire clinical investigation process	
		Implementation of Risk control measures including pre-clinical clinical investigation design changes	
		Training required to handle the investigational device should be defined and provided as necessary	
		Risk management principles must be applied to both planning and conduct of the clinical investigation	

Reference:

ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice.

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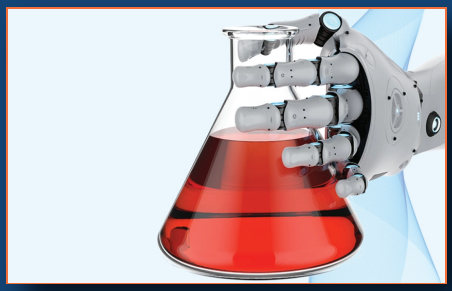
Additional Resources:

Virtual Clinical Trials : Everything You Need to Know (Whitepaper)



Integrating Quality into the Clinical Workflow (Whitepaper)

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