Risk Management

Key Changes in Good Clinical Practice [ICH E6(R3)]

This infographic highlights key changes to the risk management elements within Good Clinical Practice Version 2 and 3. Infographic based on Version 3 (draft dated 19 May 2023).

	As described in ICH E6(R2)	As described in ICH E6(R3) draft	Summary of Impact
Quality Management	Concept introduced focusing on trial activities essential to participant safety and data reliability	Quality by Design (QbD), introduced in ICH E8, has an expanded definition with the objective to apply a proportionate approach and to focus risk management efforts on what matters most	Clear link between risk-proportionate approaches adopted in quality management across the trial lifecycle and the contribution to QbD
Risk Management	Risk management established as a process	Risk process connected from Critical to Quality (CtQ) → Risk → Control	Expanded scope of risk management and principles introduced in ICH E8, connecting risk management and QbD prior to trial initiation
Critical Data and Critical Process Identification	Factors specific to critical data and processes introduced	Broader choices for what may be considered CtQ to inform discussion on risk proportionality	Critical data and processes become a subset of CtQ factor identification

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Risk Identification	Limited to processes and data at the system and trial level	→	Clarified that any type or level of risk may have meaningful impact	→	Focus on risks that have a meaningful impact
Risk Evaluation	Used the term error, which implies any mistake should be evaluated	→	Harm/hazard terminology introduced to prioritize risks that may have a meaningful impact	→	Change in terminology to demonstrate the importance of a proportional approach focused on impact
Risk Control	Controls applied based on significance of risk to subject safety and reliability of trial results. Concept of Quality Tolerance Limit (QTL) introduced	→	Concept of Acceptable Ranges introduced, which expands the QTL concept	→	Acceptable Range terminology allows for a broader range of control measures to be applied

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Risk Communication	Documentation and communication of quality risk management	→	Communication of quality management activities as needed for effective control	→	Proportional management of risk drives communication and documentation
Risk Review	Periodic review of risk controls	→	Language unchanged	→	Risk reviews should continue to ensure risk assessments are up to date and implemented control measures are relevant and effective
Risk Reporting	Reporting of the quality management approach and QTLs	→	Summarize risks and remedial actions taken in response to Acceptable Ranges	→	Emphasizing the risk-based quality management approach in the Clinical Study Report

Note: The information contained in this infographic is for general information purposes only. Users remain solely responsible for ensuring their compliance with relevant laws, regulations, and health authority guidances.

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