

# 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

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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#### 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