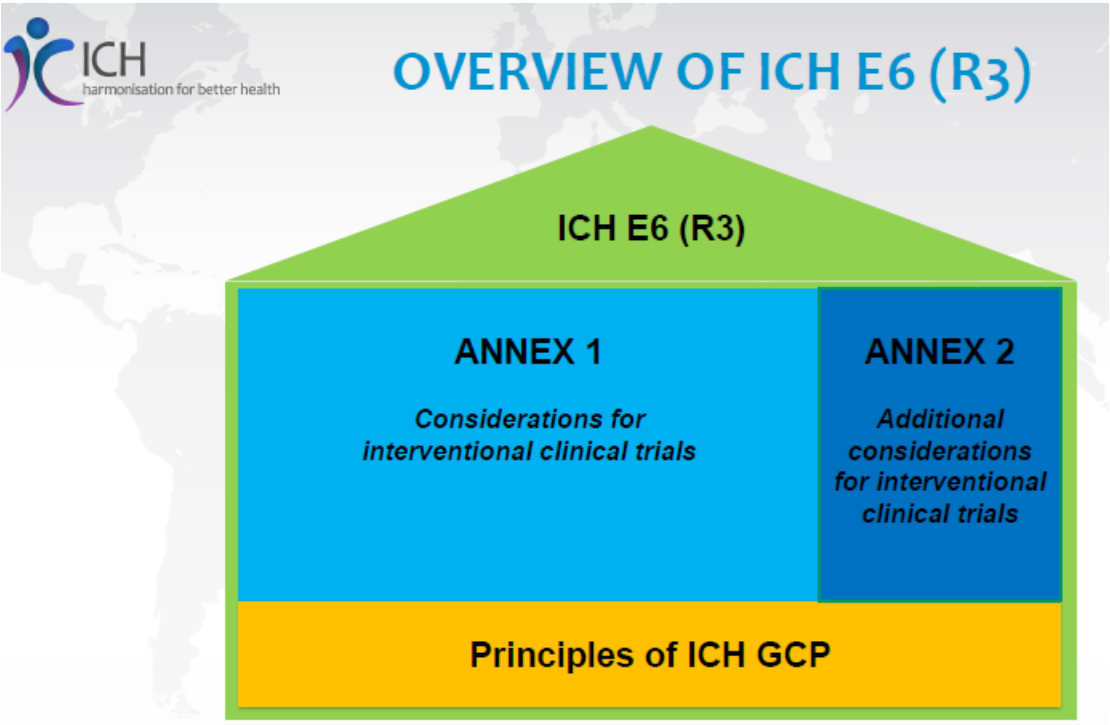
ICH GCP E6 R3: Advancing Quality and Innovation in Clinical Trials

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is currently developing the third version of its critical guideline, ICH E6 Good Clinical Practice (GCP). ICH E6 R3 aims to incorporate the latest technological advancements and innovative trial designs while upholding its commitment to protecting human participants and ensuring reliable evidence generation. This article explores the significance of quality by design in clinical trials and highlights the key aspects of the updated guideline.

Evolution and Purpose of ICH E6 R3

ICH E6 R3 comes as a response to the evolving landscape of clinical research and the need to address emerging technologies, diverse data sources, and align with other ICH guidelines, such as E8(R1) General Considerations for Clinical Studies. The previous version, E6(R2), introduced an integrated addendum focused on efficient trial design, conduct, oversight, and reporting. However, the rapid advancements in technology and trial methodologies necessitated a further update.

The draft document comprises Annex 1, which specifically addresses interventional clinical trials. Upon completion, Annex 2 will provide further guidance for "non-traditional" interventional trials, encompassing pragmatic and decentralized studies, as well as trials utilizing real-world data.



Key changes highlighted in the newly released draft:

- Quality by Design (QbD)

ICH E6 R3 places a strong emphasis on Quality by Design (QbD) by integrating quality considerations into the design phase of clinical trials. This approach ensures patient safety and data integrity right from the outset. Section 3 of the guideline provides detailed guidance on integrating QbD principles.

- Risk-Based Quality Management (RBQM)

It emphasizes the need to identify, assess, control, communicate, and review risks to trial quality at both the system and clinical trial level. RBQM enables a proactive and systematic approach to managing risks throughout the trial lifecycle. Section 5 of the guideline provides comprehensive guidance on implementing RBQM strategies.

- Critical-to-Quality Factors

ICH E6 R3 introduces the concept of critical-to-quality (CTQ) factors. These factors are essential elements that have a direct impact on the quality of the trial. The guideline outlines how to identify and ensure the maintenance of CTQ factors within acceptable ranges throughout the trial. By focusing on these critical factors, trial sponsors can enhance the reliability and credibility of trial outcomes. Section 3 of the guideline elaborates on the identification and management of CTQ factors.

- Greater Flexibility

The guideline introduces principles that support efficient trial design and conduct, with a focus on incorporating innovative digital health technologies. These technologies, such as wearables and sensors, offer new possibilities for trial implementation. However, it is important to adapt the use of technology to align with participant characteristics and the specific trial design. This may help include diverse patient populations, as appropriate, and enable wider participation.

Therefore, the revised guideline aims to enable advancements in clinical trial design and implementation, while simultaneously offering guidance to ensure the safety of participants and the generation of dependable outcomes.