ICH E6 (R3) GOOD CLINICAL PRACTICE (GCP) GUIDELINE - WHAT'S NEW?

What Should I Consider For My Clinical Trial?

- **Can my study visit schedule be simplified to align with standard care visits?**
- **Are my primary endpoint and essential data points clear?**
- **Are there clear processes for reporting high & low lab values?**

QUALITY BY DESIGN (QbD)

"Building quality into clinical trials from the start"

What does it Mean?

Proactive approach to trial planning and conduct.

Focus on what matters most for participant protection and data reliability.

FIT FOR PURPOSE

"Right tools to meet trial objective"

PROPORTIONATE, RISK-BASED APPROACHES

"Align effort with risk level and data criticality "

IMPORTANT **[For NHG Health Institution Staff Only]**

Read CITI ICH E6 (R3) GCP Training Course before 01 October 2025

ICH E6 (R3) GCP guidelines will take effect from 1 Jan 2026 in Singapore

All **NHG Health Investigators and study team members** conducting significant trial-related tasks in clinical trials regulated by Health Sciences Authority (HSA) are requested to upkeep their knowledge and understanding of GCP so as to perform the gap analysis of existing clinical trial protocols, procedures and practices. Upon completion, **upload** the CITI - GCP Cert on ECOS.

Scan Here for More Information on ICH GCP Training Requirement!

From 1 Oct 2025, NHG Health Principal Investigators (PI), Site PIs and Co-Investigators without an updated ICH E6 (R3) GCP training record will NOT be able to submit new IRB applications or study amendments for Clinical trials on ECOS.

[Submissions of sub-forms (i.e., DNC, SAE, UPIRTSO, SSR, OTH) are not impacted]

Released on 25 July 2025 **NHG Health Office of Human Research Protection Programme (OHRPP)**