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Medidata Acknowledges the Adoption and Release of ICH E6(R3) "Good Clinical Practice"

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was founded in 1990 and, since then, has acted as an agent of harmonization of global drug development. ICH's mission is to "achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner." ICH works on this mission by creating quality, safety, efficacy, and multidisciplinary guidelines. Efficacy guideline number E6 is Good Clinical Practice (GCP), critical to all clinical research operations. GCP was first adopted in 1996 and underwent one revision (R2) in 2016. In May 2023, ICH made the draft GCP Revision 3 (R3) available for public consultation. Medidata contributed to this dialogue through our multipronged membership of trade organizations (see Medidata's July 2023 statement).

The ICH E6(R3) "Good Clinical Practice" Guideline reached Step 4 (adoption) of the ICH Process on 6 January 2025 and was published on January 14, 2025. Implementation (Step 5) is subject to varying periods by ICH member nations. Medidata welcomes the finalized revision of GCP R3 and will continue to ensure our platform enables compliance by our clients and researchers. Although the implementation periods differ by jurisdiction, we will provide detailed compliance positions on the updated/revised provisions of GCP shortly within the implementation period and address any potential gaps with mitigations. In addition, we welcome the opportunity to speak to stakeholders on approaches to implementation and shared challenges and opportunities to better the clinical research experience for trial patients, researchers, and other stakeholders alike.