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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, the draft GCP Revision 3 (R3) was made available for public consultation, and 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.

Here is the link to Medidata's statement concerning the draft version released in 2023: https://www.medidata.com/en/life-science-resources/medidata-blog/medidata-welcomes-ich-gcp-e6-r3/

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one revision (R2) in 2016. In May 2023, the draft GCP Revision 3 (R3) will be open for public consultation.

The release of the draft R3 of the GCP guideline marks a step forward in modernizing clinical research and patient centricity. The patient terminology of GCP also changes, as ICH now refers to “trial patients” rather than “subjects,” highlighting patients' recognized role as stakeholders in the research process.

The document leverages a “media neutral” approach to outlining the fundamental principles of clinical research, as the aim is for the GCP R3 text to “remain relevant as technological and methodological advances occur.” This updated approach provides insight into the reason behind the revision, which the MHRA summarizes as “to address the application of GCP to new trial designs and technological innovations and to strengthen a proportionate risk-based approach of its application for clinical trials of medicines to support regulatory and healthcare decision-making.”

The draft outlines Annex I, which covers interventional clinical trials. Annex II, which will be in development soon, will cover additional considerations for non-traditional interventional clinical trials.

The ICH GCP (E6)R3 principles have been revised to reflect the new strategy that allows for flexibility to adapt to evolving trial approaches while preserving the fundamental principles of ensuring the rights, safety, and well-being of patients and data quality with a risk-based approach tailored to the specific trial.
Substantial updates to the investigator-oriented section 2 include a new addition to include eConsent options. Section 2.12 on records also outlines the various ways the investigator should ensure data integrity.

One of these novel approaches has involved industry work on making decentralized clinical trials accessible to the patients who would benefit from this opportunity through collaborative projects and regulatory engagement. It’s promising to see the industry’s work culminate in ‘trials with decentralized elements’ being referenced as an example of trial design options.

Medidata & ICH GCP (E6)R3

An area that Medidata has been very forward-thinking in and deeply engaged in is the global acceptance of eConsent and transparency in the regulatory landscape. As such, it’s a positive addition to see that the informed consent process is defined as one that “may involve a physical signature or an electronic signature,” and remote consent is considered an option where appropriate. In section 1.1.2, which outlines which information should be reviewed by the IRB/IEC (institutional review board/ independent ethics committee), subsection (d) includes in the list not only all the “information to be provided to the trial patient(s),” but also “a description of the media through which such information will be provided.”

The sponsor section illuminates the ICH principles on agreements in section 3.6, which outlines the relationship between the sponsor and service providers—a list that now includes CROs. The monitoring section 3.11.4 also opens the possibility of conducting certain on-site monitoring activities remotely, keeping the trial design and monitoring strategy in mind.

Centralized monitoring is woven into the monitoring section. It is portrayed in R3 as an essential aspect of the monitoring process, unlike the prior R2 reference to its use in exceptional circumstances. Data handling section 3.16.1 further solidified the requirement for data flow maps to be pre-specified for trials, which has been previously mentioned in GCP Symposia meetings and inspired the ACRO DCT data flow maps project by the ACRO DCT Working Party, which Medidata chairs.

ICH GCP (E6)R3 also introduces a completely new section to GCP, section 4 on Data Governance, which emphasizes data life cycle elements such as metadata, audit trail data corrections, data transfer, exchange, and migrations, and computerized systems and their security and validation.

As part of the Accelerating Clinical Trials in the EU initiative (ACT EU), the EMA hosted a stakeholder workshop on the ICH GCP (E6)R3 draft—a welcomed opportunity to engage with industry colleagues and the EMA on the R3 document in July 2023. The workshop summarized the GCP renovation, details of the public consultation, and break-out sessions, allowing regulators to hear the industry's voice at this early stage. Medidata has consistently been dedicated to actively participating in the industry's effort to connect clinical research with the potential of novel technologies and scientific approaches to foster collaboration-powered innovation.

Our fast-evolving world is full of potential to integrate novel approaches to improve existing science, and it's encouraging to see global regulatory authorities effectively and thoughtfully positioning the life sciences industry so that the fundamental guiding ethical and quality principles persist in a future-proof manner regarding novel and emerging ways of conducting research.