ICH E6(R3) Guideline Availability Notice

Thank you for your interest in ICH E6(R3) Good Clinical Practice.

The ICH E6(R3) Expert Working Group (EWG) has developed and drafted a revised guideline while considering a variety of clinical trial designs and settings. The EWG intends to encourage the use of innovation and technologies that have the potential to make clinical trials more efficient.

We greatly appreciate your comments. As we anticipate an extraordinarily large number of comments, we strongly encourage you to consider the following when drafting your comments:

- Prioritizing or highlighting key comments.
- Correlating your comment with the corresponding line number of the draft guideline to make it easier for us to identify relevant text.
- Providing justification and any relevant examples to support suggested changes.
- Consolidating comments from the same organisation, if appropriate.

We are requesting inputs across all topics addressed in this draft guideline, but please focus on key issues and consider providing insights on:

- Areas that may need additional clarity or language that may be susceptible to misunderstanding.
- Areas that may not accommodate technological innovations and design elements that are being explored to make clinical trials more efficient (we welcome examples to help inform us).
- Training components that should be included to make global GCP training useful as the EWG is planning to develop training materials for ICH E6(R3).