

ICH PRESS RELEASE

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ICH Consults with Stakeholders on Plan to Modernise Global Good Clinical Practice Guidance

The International Council for Harmonisation (ICH) announces the availability of its reflection paper on Good Clinical Practice (GCP) “Renovation”. ICH is inviting public review and comment on this paper, which contains the ICH proposal for further modernization of the ICH Guidelines related to clinical trial design, planning, management, and conduct. The scope of the proposed renovation includes the current *E8 General Considerations for Clinical Trials* and further revision to the *E6 Guideline for Good Clinical Practice, which is already undergoing modernization with the recent production of ICH E6(R2)*. Details of the proposed renovation are outlined in a reflection paper which is available on the [ICH website](#).

The goal of the potential renovation is to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of study types and data sources that are being employed to support regulatory and other health policy decisions, as appropriate. The underlying principles of human subject protection and data quality would remain. ICH’s decision to invite stakeholder comment on the proposed renovations at this early stage, ahead of guideline development efforts, recognises the considerable stake and relevant expertise in the research community beyond ICH.

The seeking of stakeholder comment on the current reflection paper is seen as a first step in an enhancement of the ICH process with respect to public consultation for the revision of ICH E8 and E6. The GCP Renovation reflection paper outlines additional steps that are also being considered to enhance stakeholder engagement.

Stakeholders are invited to submit any comments to gcprenovation@ich.org. All comments should be submitted before the closing date for public comment, which is **March 11, 2017**. ICH will review the comments received to determine whether to make revisions to the currently proposed approach. The aim is to proceed with initiating needed renovation work as soon as practical, for example, within the next year.

NOTES FOR EDITORS

This press release, together with the ICH Reflections Paper, and can be found on its website: www.ich.org

For further information, please contact the ICH Secretariat at pressrelease@ich.org

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