

ICH Press Release

ICH to Hold Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials

Geneva, 12 August 2019

ICH is announcing a public meeting entitled “ICH Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials.” The purpose of the public meeting is to provide information and solicit input from a broad range of non-ICH Member/Observer stakeholders on the draft revised E8(R1) Guideline “General Considerations for Clinical Trials.” The meeting will take place on October 31st, 2019, 8:30 – 18:00, at the headquarters of FDA, United States in Silver Spring, MD, USA. Participants can register to attend in-person or via webcast, pending available space.

In January 2017, the ICH Assembly endorsed the ICH Reflection Paper on [Good Clinical Practice \(GCP\) Renovation: Modernisation of ICH E8 Subsequent Renovation of ICH E6](#), further to which ICH initiated a revision of the E8 Guideline to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources being employed to support regulatory and other health policy decisions, while retaining the underlying principles of human subject protection and data quality.

The first version of ICH E8 Guideline was adopted in 1997 and sets out general principles on the conduct of clinical trials. Since its finalisation, clinical trial design and conduct have become more complex, impacting the time and cost required to develop drugs. An increasingly wider range of both trial designs and data sources play a role in drug development and are not adequately addressed in the original E8 Guideline.

In May 2019, the E8(R1) draft Guideline was released for public consultation, and as part of the consultation process, and in line with the ICH Reflection Paper on GCP Renovation, ICH will hold public meetings before the finalization of the revised E8 Guideline. This will allow important concerns expressed by stakeholder groups, not represented in ICH, to be further discussed and feed into the essential modernization of these foundational guidelines.

More information, including on how to register, is available on the [ICH website](#).