Global public meeting on draft ICH guideline on clinical trials

Share

News 30/08/2019

The global guidance for the conduct of [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial) is currently undergoing a major revision. As part of the worldwide consultation process, the [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)](https://www.ich.org/home.html) is organising a [public meeting to review its draft E8 (R1) Guideline ‘General Considerations for Clinical Trials’](https://www.eventbrite.com/e/ich-global-meeting-on-e8r1-general-considerations-for-clinical-trials-tickets-65824068561). EMA is encouraging its stakeholders to register for this meeting, which will be held on 31 October 2019 at the United States [Food and Drug Administration (FDA)](https://www.fda.gov/home) headquarters in Silver Spring, Maryland, United States of America. Participants will be able to attend in person or via webcast.

The [ICH E8 guideline](https://www.ema.europa.eu/en/ich-e8-general-considerations-clinical-studies) sets out general scientific principles for the conduct, performance and control of [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial). In recent years, [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial) have undergone a radical transformation with a wider range of both trial designs and data sources being used in drug development. Therefore, [ICH](https://www.ema.europa.eu/en/glossary/ich) initiated a revision of the E8 [guideline](https://www.ema.europa.eu/en/glossary/guideline) to address all the aspects that were not covered by the current version of the guidance.

The revision aims to provide up-to-date and flexible guidance on [clinical trial](https://www.ema.europa.eu/en/glossary/clinical-trial) designs and data sources that can support regulatory and other health-policy decisions while ensuring that fundamental principles, such as the protection of [clinical trial](https://www.ema.europa.eu/en/glossary/clinical-trial) participants and assurance of data quality, are maintained.

This is the first step outlined in the process of renovation of [good clinical practice](https://www.ema.europa.eu/en/glossary/good-clinical-practice) (GCP), described in the [ICH reflection paper on GCP "Renovation"](http://www.ich.org/ichnews/newsroom/read/article/ich-reflection-on-gcp-renovation-modernization-of-ich-e8-and-subsequent-renovation-of-ich-e6.html). The [reflection paper](https://www.ema.europa.eu/en/glossary/reflection-paper) contains the [ICH](https://www.ema.europa.eu/en/glossary/ich) proposal for further modernisation of the [ICH](https://www.ema.europa.eu/en/glossary/ich) [guidelines](https://www.ema.europa.eu/en/glossary/guideline) related to [clinical trial](https://www.ema.europa.eu/en/glossary/clinical-trial) design, planning, management, and conduct. The scope of the proposed renovation includes the current E8 [guideline](https://www.ema.europa.eu/en/glossary/guideline) and further revision to the E6 [Guideline](https://www.ema.europa.eu/en/glossary/guideline) for [Good Clinical Practice](https://www.ema.europa.eu/en/glossary/good-clinical-practice).

The [draft revised E8 guideline](https://www.ema.europa.eu/documents/scientific-guideline/draft-ich-guideline-e8-r1-general-considerations-clinical-studies-step-2b_en.pdf) was released for public consultation in May 2019 and it will remain open until 30 September 2019.

The purpose of the public meeting is to provide information and gather feedback from a broad range of stakeholder groups not represented in [ICH](https://www.ema.europa.eu/en/glossary/ich). The viewpoints and concerns expressed by external stakeholders will feed into the revision process of this fundamental [guideline](https://www.ema.europa.eu/en/glossary/guideline).

The meeting will be held on 31 October 2019, 8:30 – 18:00, at the FDA headquarters in Silver Spring, Maryland, USA. Participants can [register to attend in person or via webcast](https://ichglobalmeeting_e8r1_2019_eu.eventbrite.com), on a first-come, first-served basis. More information, including on how to register, is available on the [ICH website](https://www.ich.org/products/reflection-papers.html#4-2).

[ICH](https://www.ema.europa.eu/en/glossary/ich" \t "_blank" \o "The International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together regulatory authorities and the pharmaceutical industry. It makes recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration.) is an international non-profit association that brings together regulatory authorities from around the globe and experts from the pharmaceutical industry to discuss scientific and technical aspects of medicines registration to enable truly global deployment of innovative approaches in drug development.