ICH guideline development and legal standing of ICH E6 in the EU

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Health and Food Safety

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What is ICH?

- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was first launched in 1990. It underwent a major reform in 2015.

- ICH uniquely brings together regulatory authorities and pharmaceutical industry to develop harmonized ICH guidelines on scientific and technical aspects of pharmaceuticals.

- ICH currently has **23 Members and 38 Observers**.

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ICH contributes to:

- Reduction of unnecessary animal testing without compromising safety and effectiveness
- Prevention of **unnecessary duplication of clinical trials** and evaluations
- Development and manufacturing of new medicines
- Registration and supervision of new medicines

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ICH guideline development process

- ICH guidelines (of which there are over 70) are often **referred to as global standards.**

- Regulators and industry work together in developing the guidelines. Once finalized, the regulatory members in ICH are expected to implement the ICH guidelines that are complementing national/regional legislation.

- ICH Working Groups strive to reach consensus which means the final wording is often a compromise. However, in the event of no consensus, the ICH regulatory members will have the final say. The draft and final guidelines are adopted in the ICH Assembly only by the regulatory members of ICH.

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How is the EU Regulatory Network represented in ICH?

- The European Commission is one of the Founding Regulatory Members in ICH. The Commission works very closely with the European Medicines Agency which plays a pivotal coordination role in identifying the best scientific experts from the EU Regulatory Network to participate in the ICH Working Groups that are developing the ICH guidelines.

- From the selection of ICH topics for harmonization until the adoption of the ICH guidelines, the main scientific committee of the EMA, the **CHMP** (where all EU Member States are represented), is involved and gives its approvals.

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ICH E6 (R3) – a key ICH guideline

- ICH E6 (R3) guideline is one of the flagship guidelines in ICH. Its revision is part of a longer-term strategic approach referred to as the "GCP renovation" that started in 2017 with the publication of a Reflection Paper that outlined a staggered approach with revising first ICH E8 ('General Considerations for Clinical Trials') followed by ICH E6.

- The revision of E6 (R3) is part of an overall drive to **modernize clinical trial environment** and reduce the unnecessary burden, which is aligned with the objective of making the EU a more attractive place to conduct clinical trials.

- The EU is exercising leadership in the clinical trial space in ICH e.g. by holding regulatory chairmanships.

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ICH E6 (R3) – EU legislation

- The EU legislation only refers to ICH guidelines in a few instances; ICH E6 being one of them.

- The EU legislation provides that sponsors and investigators shall take appropriate account of the ICH guidelines on GCP. Moreover, all trials (EU and non-EU) submitted as part of a marketing authorization application in the EU must have been conducted in line with GCP.

- EU Member States have been provided with regular updates of the ICH E6 (R3) process in various EU Working Groups, notably the Clinical Trials Coordination and Advisory Group ('CTAG'), which is composed of the national contact points from the EU Member States as per the **EU Clinical Trial Regulation**.

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Thank you for your attention

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