ICH E6(R3) Good Clinical Practice guidance – Step 2 Public Consultation

Die folgenden Informationen sind nur auf Englisch verfügbar:

As announced by M Khair ElZarrad (PhD, MPH, Director, Office of Medical Policy - Center for Drug Evaluation and Research at FDA), on May 22, 2023, ICH-E6(R3): An Important Global Good Clinical Practice Standards draft soon becomes available for public input of the field stakeholders.

Since 2016, the year of finalization of the ICH E6(R2) Good Clinical Practice (GCP) guideline, the clinical research field faced advances in technology that came along with rising complexity of trials, and global challenges. Reasonably, the International Council for Harmonisation (ICH) Expert Working Group for ICH E6(R3) was created to address the growing gaps between the existing regulations and real-world processes, such as growing variety of study types and data sources, as well as quality concerns.

Bregnhøj, L., Sweeney, F., d the ICH EWG (2020) summarised the scope of the ongoing work on the fundamental E6(R3) amendment, with its overarching principles laid in the Annex 1, the Glossary, and in the 3 Appendices, that will replace the current E6(R2), as listed below:

Purpose of E6(R3) guideline revision:

- Developing a responsive GCP guideline
- Providing flexibility to:
  - Acknowledge the diversity of trial designs, data sources, and the different contexts in which clinical trials can be conducted.
  - Highlight that GCP principles can be satisfied in a variety of ways.

Revision of the E6(R3) includes the following:

- To rewrite and rearrange the following parts of the ICH-E6(R2) guideline:
  - Principles and Annexes: Annex 1 – GCP for interventional clinical trials (principles related to the use of approved/unapproved drugs in a controlled setting with prospective allocation of treatment to participants and collection of trial data) and Annex 2 – additional considerations for non-traditional interventional clinical trials (principles as they relate to the use of non-traditional clinical trial designs such as pragmatic CTs, as well as trials that incorporate real world data sources).
  - Align with the E8 guideline, as appropriate.
  - Bridge the known gaps within the E6 guideline and other relevant ICH guidelines.
- Clear and concise scope:
  - Expectations should be fit for purpose.
- Focus on key concepts:
  - Quality by design and Risk-based approach
  - Proportionality
  - Critical to Quality factors, etc.

The MHRA (a full member of ICH since May 2022) experts are welcoming feedback of the UK stakeholders that will be collected through the Agency's website (Fisher, A. and Wakelin-Smith, J., 2023). Clinical Research specialists from other countries will be able to provide their comments on the ICH website.

The Step 4 (Adoption of Technical Document: Principles and Annex 1) is planned in August 2023 (ICH E6(R3) EWG Work Plan, 2022).

References:

1. M Khair ElZarrad (2023) 'An Important Global Good Clinical Practice Standards draft soon becomes available for public input of the field stakeholders' [Online]. Available from: https://lnkd.in/etxNzD_e (Accessed: 23 May 2023).
2. Fisher, A. and Wakelin-Smith, J. (2023) 'ICH E6(R3) Good Clinical Practice guidance - Step 2 Public Consultation' [Online]. Available from: https://mhrainspectorate.blog.gov.uk/2023/05/02/ich-e6r3-good-clinical-practice-guidance-step-2-public-consultation/ (Accessed: 18 May 2023)
3. Bregnhøj, L., Sweeney, F., the ICH EWG (2020) 'Introduction to ICH E6(R3) and stakeholder engagement plan' [Online]. Available from: https://www.ema.europa.eu/en/documents/presentation/presentation-12-introduction-ich-e6r3-stakeholder-engagement-plan-l-bregnhoj-f-sweeney_en.pdf (Accessed: 18 May 2023).

Pressemitteilung

23.05.2023
Quelle: ICHGCP Network

Weitere Informationen

- ICHGCP Network