第41回ICH即時報告会

ICH E6(R3) IWG
GCP（医薬品の臨床試験の実施の基準）
シンガポール会合報告

2019年12月18日

PMDA信頼性保証部
E6(R3) Topic Leader
北林 アキ

改訂の概要

- 臨床試験のデザインやデータソースの多様化に対応するため、GCP刷新の一連の作業として、ICH E8（臨床試験の一般指針）の現代化に引き続き、現行のICH E6(R2)ガイドラインを改訂するもの

＜ICH Reflection on “GCP Renovation”（January 2017）より＞

- **Guideline effort 1**: Develop a revised ICH E8 guideline
- **Guideline effort 2**: Develop new ICH E6 Overarching Principles guideline.
- **Guideline effort 3**: Develop E6 Annex 1 focused on *traditional interventional* trials of investigational unapproved or approved drugs in a controlled setting with prospective collection of trial data.
- **Guideline effort 4**: Develop ICH E6 Annex 2 focused on *non-traditional interventional* trials and/or data sources.
- **Guideline effort 5**: Develop ICH E6 Annex 3 focused on *non-traditional* trial designs.

http://development.ich-public-backend.dev8.penceo.com/sites/default/files/2019-04/ICH_Reflection_paper_GCP_Renovation_Jan_2017_Final.pdf

経緯

- 2019年6月
  - アムステルダム会合にて，新規トピックとして採択

  （提案団体：FDA）
- 2019年11月17日～20日（4日間）
  - シンガポールにて ICH E6(R3) Informal Working Group (IWG) 会合開催

E6(R3) IWG

- Participants
  - FDA†(3), PhRMA(1), EC‡(2), EFPIA(2), MHLW(0)/PMDA(2), JPMA(2), Health Canada(1), IGBA(2), Swissmedic(1), ANVISA of Brazil(1), IFPMA(1), NMPA pf China(1)
    TFDA of Chinese Taipei(1), HSA of Singapore(1)

    WHO(1), CDSCO of India(1), TGA of Australia(1), TITCK of Turkey(1)

    † Rapporteur ‡ Regulatory Chair

- 日本側メンバー
  - MHLW/PMDA
    TL: 北林 アキ（PMDA）
    DTL: 山崎 恵里子（PMDA）
  - JPMA
    TL: 青柳 充顕 （エーザイ株式会社）
    DTL: 川勝 英次 （第一三共株式会社）

参考
TL: Topic Leader
DTL: Deputy Topic Leader

シンガポール会合の目的と成果

- 目的

  新たな ICH Topic としての活動を開始するため,

  ✓Concept Paper

  ✓Business Plan

  を IWGとして作成し、Management Committee (MC) の承認を得ること。

- 成果

  シンガポール会合にて、IWGで合意した上記文書は、MCに承認された。

Concept Paper (1)

Issues to be Resolved

- Overarching Principles and Objectives
- Annex 1 - Interventional clinical trials

現行のR2を置き換えるもの

This will include the use of unapproved or approved drugs in a controlled setting with prospective allocation of treatment to participants and collection of trial data. This Annex will be developed simultaneously with the principles and objectives document to ensure consistency and to provide stakeholders with a complete package that can replace E6(R2); and

- Annex 2 - Additional considerations for non-traditional interventional clinical trials

追加の考慮が必要な点

This will include designs such as pragmatic clinical trials and decentralized clinical trials, as well as those trials that incorporate real world data sources. Before the drafting of Annex 2, its scope will be further clarified, to define the nature of trials involved, in an update to this concept paper.

Concept Paper (2)

- **Type of Expert Working Group and Resources**

The EWG will include experts from various disciplines including clinical, statistical, data science, clinical outcomes assessment, regulatory compliance, and potentially others. The group should have overlap of expertise with the experts of the E8 EWG and work in close collaboration with them. The work of the group will involve engagements with a variety of stakeholders including academia and patient advocacy groups throughout the development process.

様々なステークホルダーの意見を取り入れながら検討を進める

Concept Paper (3)

- **Issues to be Resolved**

The proposed E6(R3) revision work will initially involve the simultaneous development of the overarching principles and objectives document and the first annex to produce a unified package to replace ICH E6(R2).

- **Timing**

It is anticipated that the process to create the overarching principles and objectives document and Annex 1 is expected to take 18 - 24 months to reach Step 1, once the concept paper and business plan are endorsed. After the priniciples and objectives document and Annex 1 complete step 1, the work on Annex 2 will commence.

・Principles & ObjectivesとAnnex 1を同時に検討

・Principles & ObjectivesとAnnex 1までがステップ1に到達した後、Annex 2の検討を開始

今後の予定

- マイルストーン
  - 2019年 12 月～ Web会議
  - 2020年5月: Face-to-face会合（@バンクーバー）
  - 2021年5月～11月:Annex 1までについて Step 1 到達

ご清聴，ありがとうございました。