Clinical Trial Topic

China and Japan Regional Joint Public Meeting on ICH

2021 June 18

Experts

Dr. Zhimin Yang
Center for Drug Evaluation
NMPA,China

Dr. So Miyoshi
Pfizer R&D Japan
JPMA

Dr. Haiyan Li
Peking University
Third Hospital

Dr. Ao Peng
Pfizer Investment Co. Ltd.
RDPAC, China

Progress of ICH E topics

(Chinese Prospective of Incheon Meeting)

Dr. Zhimin Yang
ICH E6(R3)EWG Expert
Center for Drug Evaluation NMPA
2021 Jun. 18

Outline

- 1.Updates on E topics from Incheon meeting that Chinese experts participated
  - Current status
  - Highlights of discussions
  - Next step
- 2.Local efforts of Chinese EWG members in the past 6 months
- 3.Issues that Chinese regulatory authority are facing
- 4.Expectation for the future

Updates on E topics from Incheon meeting that Chinese experts participated

- Scheduled in Incheon, Republic of Korea
- Virtual Meeting instead
- From late May to early June

Current status

- E Topics that Experts engaged during Incheon Virtual Meeting :

E Topics	Current Status
E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	Step 1*
E6(R3): Good Clinical Practice(GCP)	Step 1*
E11A: Pediatric Extrapolation	Step 1*

Note：* stands for E topics that Chinese experts participated during the Incheon Virtual Meeting

Highlights of discussions-E2D(R1)

- Concept Paper Endorsed by MC on 31 January 2020
- During Incheon Virtual Meeting, small drafting groups within the EWG had updated their progress. Thorough discussion was made on detailed concepts

Final Concept Paper
E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
Endorsed by the Management Committee on 31 January 2020

Type of Harmonisation Action Proposed

An update of the existing ICH E2D (Post Approval Safety Data Management: Definition and Standards for Expedited Reporting E2D) guideline is proposed to clarify the management of post-approval safety information from new or increasingly used data sources including the need to adapt definitions and standards.

Statement of the Perceived Problem

The ICH E2D guideline was agreed in May 2003. In the meantime, new sources of post-approval safety information have emerged or are more frequently applied (e.g. social media, market research programs, patient support and assistance programs) which vary in characteristics and contribution to quality of post-approval safety information. The definitions and regulatory guidance in ICH E2D are no longer sufficient to provide guidance on the current practices and needs. Therefore, the definitions and standards for the management of post-approval safety information need to be revisited in order to support appropriate safety surveillance and actions.

Issues to be Resolved

Careful consideration and regulatory guidance are needed by adapting the existing concepts, principles and definitions of the ICH E2D guideline to the management of new sources of safety information.

In addition, there is also an opportunity to adapt the guideline to address other issues which may include, but are not limited to:

- ambiguous, out of date or missing definitions and terminology,
- sources of ICSRs,
- standards for post-market regulatory reporting,
- good case management practices (e.g. detection and management of duplicate reports, identifiability of patients and reporters, management of literature reports, observations with no associated adverse outcome and outcome-only reports)

Source: https://database.ich.org/sites/default/files/E2D-R1_ConceptPaper_Final_2020_0115.pdf

Highlights of discussions-E11A

- Concept Paper Endorsed by MC on 3 October 2017
- EWG has basically reached consensus on the contents of the step 1 draft.
- Yet the words are still being refined by the whole group to reach the final version during this meeting.

Final Concept Paper
Pediatric Extrapolation
3 October 2017
Endorsed by the Management Committee on 17 October 2017

Type of Harmonisation Action Proposed: New Efficacy Guideline under E11: E11A Clinical Investigation of Medicinal Products in the Pediatric Population

Statement of the Perceived Problem

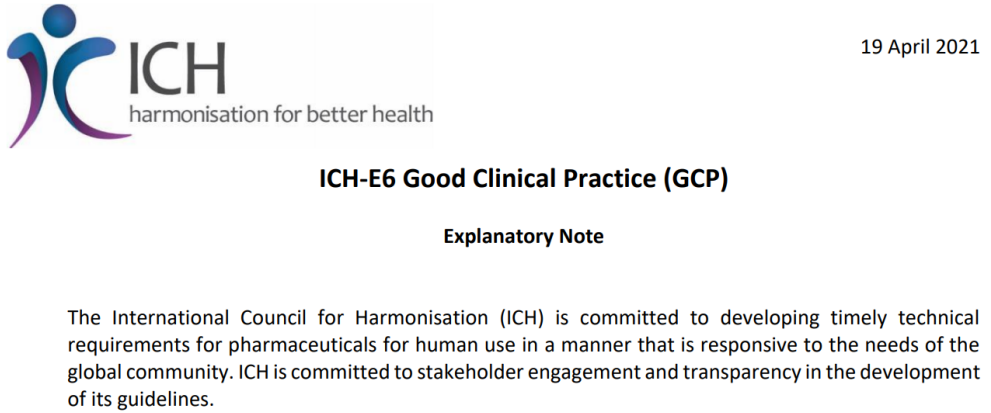
In both the US and EU, pediatric legislation has increased the number of approved drugs with specific efficacy and safety data in labeling for pediatric populations. However, in many cases, there is still a long gap (between 7-10 years) between the initial adult approval and the inclusion of pediatric-specific information in product labeling. The use of pediatric extrapolation has advanced substantially as an approach to improve the efficiency and success of pediatric drug development. However, there is variability in the interpretation and application of extrapolation across regulatory authorities. Harmonization of methodologies and strategies to incorporate pediatric extrapolation into overall drug development plans will improve the speed of access to new drugs for pediatric patients.

The current E11(R1) concept paper recommends that more detailed guidance be developed to advance the use of pediatric extrapolation. The current E11(R1) guideline only includes a high level description of pediatric extrapolation that encourages sponsors to initiate a

Source: https://database.ich.org/sites/default/files/E6-R3_FinalConceptPaper_2019_1117.pdf

Highlights of discussions-E6(R3)

- Draft Principle has been published in Apr.2021


ICH
harmonisation for better health

19 April 2021

ICH-E6 Good Clinical Practice (GCP)

Explanatory Note

The International Council for Harmonisation (ICH) is committed to developing timely technical requirements for pharmaceuticals for human use in a manner that is responsive to the needs of the global community. ICH is committed to stakeholder engagement and transparency in the development of its guidelines.

- A Public Web Conference was held on 18 and 19 May 2021 to promote the principle and introduce the progress and plan of the EWG.


ICH E6 Guideline for Good Clinical Practice – Update on Progress

MAY 18, 2021 TO MAY 19, 2021

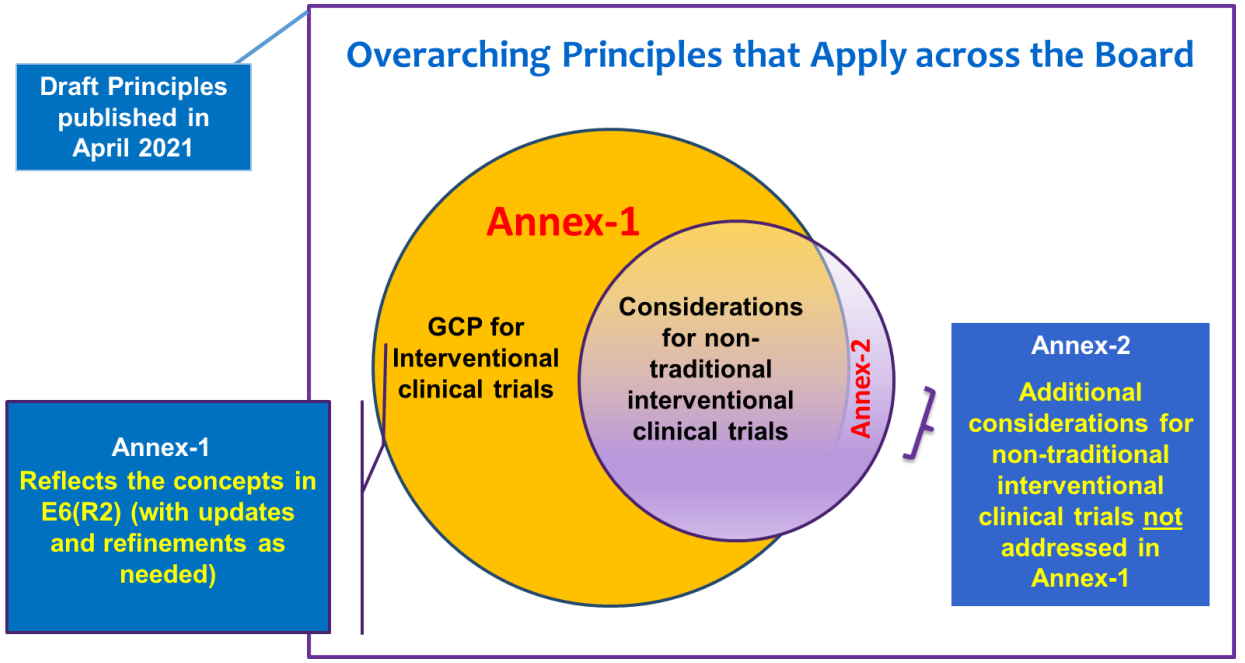
CTTI PROJECT: INFORMING THE UPDATE OF ICH E6

Source: https://database.ich.org/sites/default/files/ICH_E6-R3_GCP-Principles_Draft_2021_0419.pdf
https://www.ctti-clinicaltrials.org/briefing-room/meetings/ich-e6-guideline-good-clinical-practice-%E2%80%93-update-progress

Highlights of discussions-E6(R3)

- EWG has initiated the draft of *Annex1-Interventional clinical trial*

- Based on the gap analysis, three topics, Data Governance, Responsibility, Monitoring has been identified to draft first



Source: https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/5.18-19.2021_ich_update_final_slide_deck.pdf

Highlights of discussions-E6(R3)

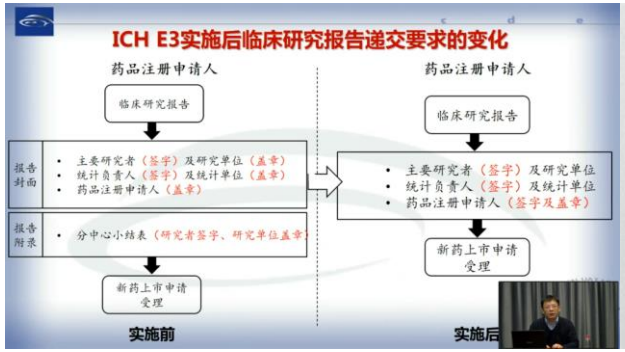
- Small drafting groups have been formed in early 2021 and progress has been made
- All three drafting group reported their progress and issues to be discussed and decided by the EWG during Incheon Virtual Meeting
- A reflective discussion was made on scope, concepts, wording around these three topics and some issues regarding the drafting direction has been decided
- EWG will keep on drafting and keep an active engagement with stakeholders

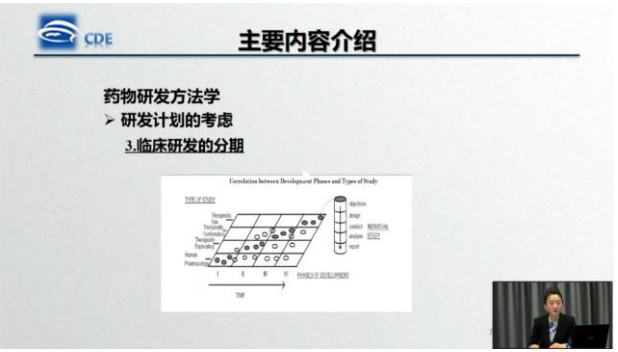
Next Step

E Topics	Next Step
E2D(R1): Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	The EWG will continue drafting the technical document and share the combined draft to the whole EWG before Aug. 2022.
E6(R3): Good Clinical Practice(GCP)	Principles and Annex 1 are planned to reach step 1 and step 2a/b in Jan. 2022,then discuss the schedule for Annex 2
E11A: Pediatric Extrapolation	Planned to reach step 1 and step 2a/b in Nov. 2021

Recent Local efforts of Chinese EWG members

- Public consultations on opinion, implementation and translation of Guidance (E9(R1) E14-S7B etc.)
- Promotion of ICH public conference(E6(R3))
- Web Training Sessions to promote the implementation(E3(R1),E6(R2),E4, E9,E5(R1),E17,E8,E10,E1 etc.)





Picture Source: Center for Drug Evaluation Site

Recent Local efforts of Chinese EWG members

- 2021 China DIA ICH Day
- ~1000 audiences on site or online
- Chinese EWG Experts actively engaged with industry and academia on implementation and progress of E17,E9(R1),E6(R3) etc.
- Profound discussions that would enrich future works of EWG and strengthen the implementation

Picture Source: DIA China

Issues that Chinese regulatory authority are facing

- 1. E guidance harmonized back in days may not adapt to rapid and vast innovations in every aspects of clinical trial. This could lead recent implemented guidance unable to fit some current situation.
  - Basing on global cumulative experiences, revision to present guidance or new guidance is highly welcomed to sought the new consensus.

Issues that Chinese regulatory authority are facing

- 2. Discrepancy of understanding towards the same guidance among stakeholders while implementation
  - In China alone, capability of regulator, companies, investigators, site staff varies significantly, thus the mutual understanding towards the same guidance might not be easy to reach
  - Such discrepancy would be more obvious as we dive deeper into the global pharmaceutical development and cause differences

Expectation for the future

- 1.Pursuing more in-depth exchanges and promote understanding with global regulatory authorities, industry and academia.
- 2.Refinforce training efforts to establish consensus in clinical trial community locally, regionally and globally. So as to advance the implementation and promote the adherence to E topic guidance.
- 3.Actively engaged with new ICH topic harmonization

Thank you!