efpia
European Federation of Pharmaceutical Industries and Associations

IMPLEMENTATION OF THE ICH E17 GUIDELINE ON PLANNING AND DESIGN OF MULTI-REGIONAL CLINICAL TRIALS IN INTERNATIONAL MARKETS

WHY THIS IS IMPORTANT?

Drug development now takes place on a global scale. The number of clinical trials has expanded rapidly over the last decade, and this increase is especially notable for Asia.

The ICH E17 Guideline on Planning and Design of Multi Regional Clinical Trials (MRCTs) is an important tool for global drug development and registration.

HOW CAN WE SPEED UP GLOBAL DRUG DEVELOPMENT AND REGISTRATION?

In a recent Position Paper on Implementation of the ICH E17 Guideline on Planning and Design of MRCTs (November 2021), EFPIA identified the following recommendations to support faster global drug development and registration.

- Stakeholders, including regulators and sponsors, should use the ICH E17 recommendations to optimise drug development at a global level.
- **TRAINING:** Promote greater awareness and use of E17 training materials.
- **POOLING STRATEGIES:** Adoption of strategies that pool patients across a region (for example, from Japan, South Korea, and China into an East Asian region), provided that ethnic factors are adequately understood and comparable and align with the recommendations of the ICH E5 Guideline.
- **LOCAL REQUIREMENTS:** Regulatory authorities adequately implement the ICH E17 guideline, and make sure to adapt their local laws and guidelines to the principles of the E17 guideline where appropriate.

An EFPIA survey conducted in 2020 on the implementation of the E17 Guideline highlighted challenges with full implementation of the guidelines.

TRAINING: Company Awareness of Existing Training on ICH E17 Guideline

The majority of respondents indicated that the ICH E17 training materials are not being used within their companies. Furthermore, some even commented that they were not aware of the existence of these materials; others remarked that the training materials are too general, because they are not covering how to better adhere to the ICH E17 principles in practice.

In your view, are the ICH E17 training materials being utilised within your company?

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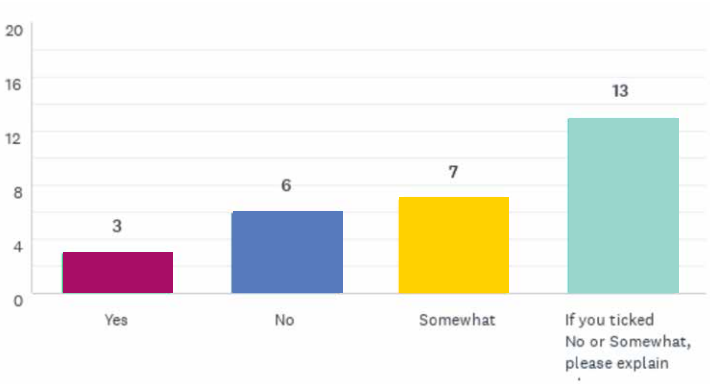

Key message:
Limited use of training materials (20%).

A clear opportunity to encourage greater awareness and use of ICH E17 training materials in companies.

POOLING STRATEGIES: The ICH E17 Guideline Introduced a New Concept of a "pooled region/pooled subpopulation"

The survey explored different aspects covered by the guideline. Respondents were asked to rate how well various aspects had been applied in practice on a scale of one to four (four being best) in the different countries. Pooling strategies—the prespecified pooling of regions or subpopulations that may help provide flexibility in sample size allocation to regions, facilitate the assessment of consistency in treatment effects across regions, and support regulatory decision-making—emerged as an aspect where implementation could be improved in China, Japan, and South Korea.

How well do you believe that the regulatory authority has implemented the ICH E17 guideline with respect to each aspect? (on a scale of 1 – 4; 4 being best)

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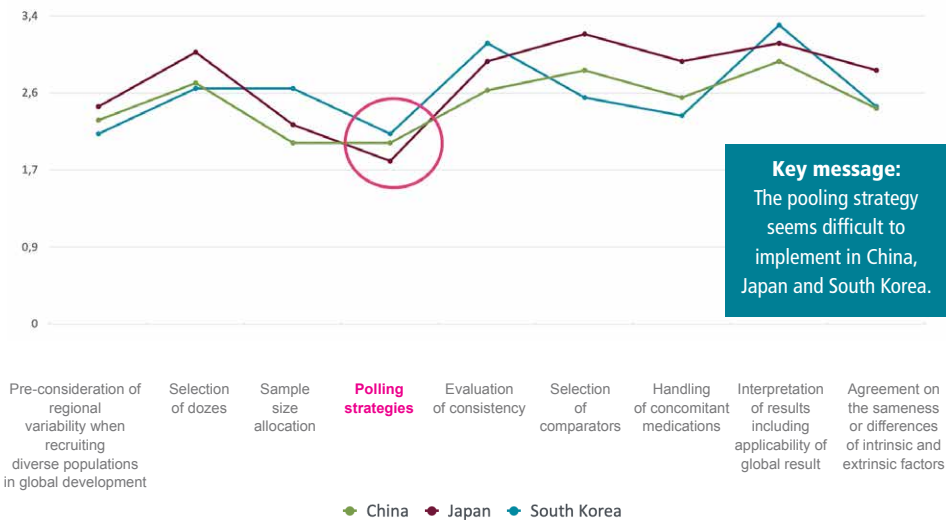

Key message:
The pooling strategy seems difficult to implement in China, Japan and South Korea.

The results shared for this section focus on China, Japan and South Korea due to limited data received on Brazil, India, Russia and Saudi Arabia.

LOCAL REQUIREMENTS: Perceived by Industry as a Barrier to Full Implementation of ICH E17

14 out of 15 companies mentioned that local legislation or regulation is a hindrance, followed by the lack of awareness and understanding of the guideline by regulatory authorities and operational/logistical considerations.

What do you consider the most critical hurdles for full use of ICH E17? Select the top three in your opinion.

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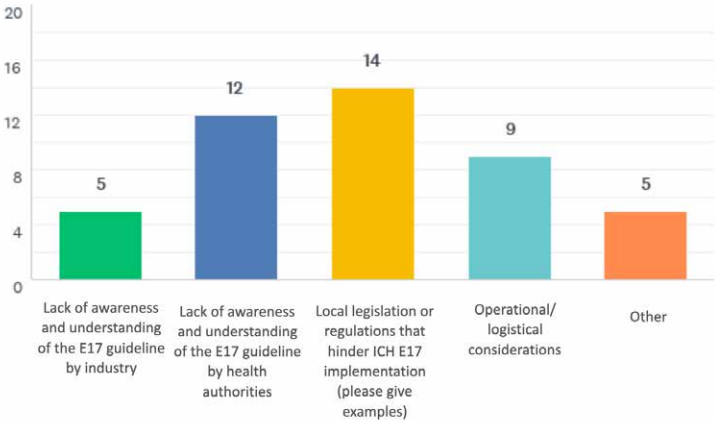

Key message:

93% of respondents reported local legislation or regulations hindering E17 implementation as a critical hurdle for full use of E17.

80% of respondents reported lack of awareness and understanding of E17 by health authorities as a critical hurdle for full use of E17.

In contrast, only 33% of respondents reported lack of awareness and understanding of E17 by industry as a critical hurdle.

WORKING TOGETHER TO DELIVER MORE FOR PATIENTS, IN EUROPE AND BEYOND

The ICH E17 Guideline is an important tool in global drug development. EFPIA encourages all stakeholders to strive for full implementation of the Guideline principles, including the ability to pool subregions/subpopulations. This will ultimately support further development of Multi-regional Clinical Trials and their acceptance by regulatory authorities globally.

Additional resources

EFPIA's presentation at the 2021 DIA Europe "ICH E17: General Principles for Planning and Design of Multi-Regional Clinical Trials"
https://efpia.eu/media/636466/e17-industry-pres-dia-euro-2021-h-nielsen_final_24feb2021.pdf