Final Concept Paper

E17 Implementation Working Group (IWG)
dated 15 December 2017

Endorsed by the Management Committee on 2 February 2018

Type of Harmonisation Action Proposed

This Concept Paper supports a proposal for the establishment of an Implementation Working Group (IWG) for the E17 Guideline.

Statement of the Perceived Problem

- Successful implementation of the principles of this guideline will be critical for achievement of its goals. Implementation will require application of consistent principles in the context of an evolving drug development environment.
    - A large number of public comments concerning different aspects of the draft guideline emphasize the critical need for further explanation of the principles.
    - Many issues raised in the comments would be better addressed through specific examples provided in training materials, rather than through providing greater detail in the guidance itself to stimulate development and advancement in study design and methodology. Areas of interest include considerations regarding planning the overall sample size, allocation of subjects to regions, impact on the ability to explore regional consistency, dose selection, pooling strategies, and choice of comparators and concomitant treatments.
    - Numerous operational issues involved in conducting such trials are not addressed in the guideline, and these types of issues could better be addressed through training materials. Training materials and other supportive measures can be more easily and frequently adjusted to reflect learnnings from completed trials and underwent regulatory assessment as compared to material that can be presented in the guideline itself.
    - The target audience of this guideline is highly diverse in terms of experiences planning and implementing MRCTs, and training materials could be optimised for specific regions and functions (e.g. clinical experts, regulators).
    - The shift in mind-set to strategic planning of global drug development starting from the early stages is critical to the formation of procedures to ensure the timely collection of key data.
    - The strategic application of MRCTs when appropriate starting from the early stages of the product development programme represents an important paradigm shift for many stakeholders. Advancement towards goal realization will need to be an active process.

- Establishment of an IWG to accomplish this will offer the following benefits:
    - Will make clear that the implementation of E17 is a priority for ICH and establishing an IWG will justify ICH stakeholders' allocation of resources to this effort;
    - Will allow for systematic budgeting for training materials and other key activities;
    - Will offer a framework allowing for potential face-to-face meetings; and
    - Will ensure the timely availability of critical training materials.

Issues to be Resolved

Many of the public comments requested additional clarification of some of the principles in the document through use of examples. Stakeholder understanding of these issues is essential and will require innovative training materials. These materials should include relevant content and also make effective use of multimedia materials (e.g., video) and content delivery methods (e.g., e-learning, workshops) as appropriate.

Availability of standardised training and presentation materials will help ensure that ICH E17 is implemented consistently and with "one voice", while still allowing for further customization as needed. Training will include continuations of presentations and seminars at relevant stakeholder meetings (e.g., events hosted by the Drug Information Association (DIA)). An IWG could consider the application of surveys to continuously assess stakeholder training needs and requirements. It is anticipated that this may be facilitated by collaboration with the ICH Training Committee.

Background to the Proposal

At the time of establishment of the E17 Expert Working Group (EWG), it was understood that international harmonisation on this topic will facilitate more appropriate MRCT execution and greater overall efficiency in drug development, resulting in fewer redundancies in drug development programs and facilitating better regulatory decision-making.

Accordingly, the formation of an E17 IWG will promote the efficient and consistent implementation of this guideline.

Type of Implementation Working Group and Resources

It is proposed that an IWG be established and tasked with the development of a strategic training plan (including the proactive identification of professional societies and other relevant organizations suitable for hosting presentations and workshops concerning ICH-E17), preparation of training materials, and ICH-E17 Q&A materials (tentative).

It is proposed that there be some overlap between the members of the E17 EWG and IWG. Broad representation of the ICH Members and Observers is encouraged. It is also proposed that other sources of expertise be included as necessary (e.g., training and communication experts, experts on clinical trial operations, and/or others representing other important stakeholder perspectives).

It is anticipated that most of the IWG's work will be conducted via webconferencing. However, a face-to-face meeting will be proposed for critical steps of the IWG's work.

Timing

• Approval of Concept Paper by Magement Committee	January 2018
• Establishment of IWG	1Q 2018
• Discussion by e-mail, web-based conference or teleconference Strategic plan; outline of training materials and initial drafts	1Q-3Q 2018
• Face-to-face IWG Meeting: finalize first set of training materials	4Q 2018
• Publication of initial training materials on ICH website	4Q 2018
• Assess remained tasks and propose the future workplan to complete the tasks	1Q 2019