Final Concept Paper

ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)
dated 14 November 2018

Endorsed by the Management Committee on 15 November 2018

Type of Harmonisation Action Proposed

This Concept Paper supports a proposal for a new harmonised guideline that specifies comprehensive clinical protocol organization with standardized content with both required and optional components. The working group will deliver the following:

- Guideline outlining two main sets of harmonised approaches
    - a template to include identification of headers, common text and a set of data fields and terminologies which will be the basis for efficiencies in data exchange
    - a technical specification that uses an open, nonproprietary standard to enable electronic exchange of clinical protocol information

Statement of the Perceived Problem

The clinical protocol describes the processes and procedures directing the conduct and analysis of a clinical study. Currently there is no internationally harmonised standard template for the format and content of the clinical protocol document to support consistency across sponsors and exchange of protocol information. This lack of harmonization contributes to inefficiencies and difficulties in reviewing and assessing clinical protocols by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. An international guideline and template would support consistency in the development of structured and unstructured protocol content, and a technical specification will facilitate its electronic exchange.

Issues to be Resolved

In order for ICH to develop an internationally harmonised guideline, template, and technical specification for the protocol, the following issues will be addressed:

- Breadth of Coordination: Coordinated input across and alignment with other E-topics including but not limited to E3, E5, E6, E8, E9, E11 and E17 will be needed. The membership and practices of the EWG will ensure proper representation of the required expertise in the discussions.

- Breadth of Studies: The guideline, template, and technical specification will cover a broad range of study types (scope to be aligned with the ICH "GCP Renovation" initiative).

- Flexibility: The need for consistency must be carefully balanced with flexibility to comply with local regulations and practices.

Background to the Proposal

ICH M2's informal monitoring of industry standards development activities, identified the need for harmonised protocol structure and content. Informal, cross-party discussions with E-topic SMEs indicate agreement on perceived value from a broadly adopted harmonised document organization supported by electronic content structured for exchange. The expectation of increased efficiencies is anticipated in most steps of study conduct (e.g., trial design, investigator on-boarding, study setup, study reporting, and review). The perceived benefit of this effort is commonly expressed by SMEs from regulators and industry.

Type of Expert Working Group and Resources

The EWG should be a multidisciplinary EWG that combines the relevant clinical study protocol and electronic technical expertise. Given the numerous connections with other ICH efforts, commitment of time and resources from other Expert Working Groups will be needed. In particular, a plenary face-to-face meeting with the M2 working group may be needed.

An IWG will be needed to implement and maintain the guideline, template, and specification on an ongoing basis, as technology and science evolve.

Timing

- Approval of the Concept Paper Outline — June 2018
- Establishment of the informal Working Group — September 2018
- First face-to-face of the informal Working Group — November 2018
- Approval of Final Concept Paper & Business Plan — November 2018
- Teleconferences of Expert Working Group (EWG) — 4Q 2018 - 2Q 2019
- Face-to-face of the EWG meetings — June, November 2019
- Teleconferences of Expert Working Group (EWG) — 3Q 2019 – 2Q 2020
- Draft Technical Document – Step 1 — June 2020