Final Business Plan

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

Endorsed by the Management Committee on 15 November 2018

1. The issue and its costs

What problem/issue is the proposal expected to tackle?

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 harmonisation 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.

What are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with "non action"? Lack of harmonization leads to inconsistent quality of protocols, resulting in…

- Delayed timelines for product development, which may delay access to medicines for patients
- Resource-intensive manual activities, which increase the cost and complexity of clinical research and drug development;
- Inefficient use of knowledge and duplication of effort, and
- Inability to leverage tools that allow reuse, review, analysis, and reporting.

2. Planning

What are the main deliverables? 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

What resources (financial and human) would be required?
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, and a designated laison may be needed. Additional expertise may be

needed for development of the technical specification. Parties may need to mobilize internal networks of subject matter experts to develop and review drafts. Resources will be needed for maintenance of the template and technical standard. Finally, resources are desired to develop e-learning modules as the guideline matures.

What is the time frame and key milestones of the project? It is anticipated that a Step 1 Technical Document comprising a Guideline, protocol template, and technical specification document will be presented for Step 1 sign-off in June of 2020, with Step 2a/2b complete by July 2020, Step 3 signoff and Step 4 adoption by November 2021, with implementation to follow in 2022.

What special actions to advance the topic through ICH, e.g. stakeholder engagement or training, can be anticipated either in the development of the guideline or for its implementation? eLearning modules are anticipated for key stakeholders on the ICH website; key stakeholder engagement for this topic will also be critical; appropriate mechanisms will be used to ensure awareness of key stakeholders of opportunities to comment.

3. The impacts of the project

What are the likely benefits (social, health and financial) to our key stakeholders of the fulfilment of the objective? A harmonised clinical protocol and specification for electronic exchange of protocol information will enhance the ability of sponsors, regulators, investigators, and other stakeholders to initiate, review, and conduct clinical research, resulting in more efficient drug development and delivery of medicines to patients.

What are the regulatory implications of the proposed work – is the topic feasible (implementable) from a regulatory standpoint? A harmonised clinical template is feasible and can be implemented.

Will the guideline have implications for the submission of content in the CTD/eCTD? If so, how will the working group address submission of content in the dossier? Will a consult be requested with the ICH M8 working group? While specific details will depend on the final technical specification, ongoing consultation with the M8 EWG will be needed.

4. Post-hoc evaluation

How and when will the results of the work be evaluated?

- *When*: After implementation of local regulations and/or guidance documents that align with the final guideline.
- *How*: Ad hoc feedback from stakeholders.