ICH M11: Clinical electronic Structured Harmonised Protocol (CeSHarP)

PUBLIC WEBINAR REPORT

January 26, 2023

INTRODUCTION

The ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP) Expert Working Group (EWG) held a public webinar[1] on January 26, 2023, with 1,765 registrants. This webinar provided a public introduction to the ICH M11 Guideline as it has achieved Step 3 of the development process. The webinar was scheduled to align with the timing of the U.S. regional open public consultation period that opened on December 22, 2022, and closed on February 21, 2023.

The Guideline on the clinical protocol specifies a comprehensive, organized structure with standardized content, including required and optional components. In addition to the Guideline, ICH M11 deliverables include a Protocol Template, with headers, common text, and a set of data fields and terminologies, as well as a Technical Specification that uses an open, nonproprietary standard to enable the electronic exchange of clinical protocol information. The protocol template will be a useful tool particularly for clinical investigators running smaller clinical trials (i.e., academia). This webinar was intended to reach academic researchers and other clinical investigators that are not represented on the ICH M11 EWG.

This report highlights key points from the EWG on the development of the Guideline, Protocol Template, and Technical Specification.

WEBINAR OVERVIEW

During this webinar, EWG members explained the benefits and opportunities that will be created for stakeholders with the electronic exchange capabilities of an internationally harmonised structured protocol template. To date, there is no internationally harmonised standard for the format and content of clinical protocols. The webinar closed with a question and answer (Q&A) session in which EWG members answered common questions participants submitted during registration.

SESSIONS

Overview of M11 Guideline

The first session opened with an introduction to ICH, including the organizational structure and governance, members, and accomplishments. The introduction was followed by an overview of ICH M11 work to date, the EWG, and deliverables including the Guideline and associated

[1] The public webinar was convened by the Clinical Trials Transformation Initiative (CTTI), which is a public-private partnership co-founded by the U.S. Food and Drug Administration (FDA) and Duke University in 2007.

documents. Finally, the M11 Guideline objectives and scope were discussed. The Guideline describes the approach used to develop the M11 Clinical electronic Structured Harmonised Protocol (CeSHarP) Template and Technical Specification.

Protocol Template

The second session provided an overview of the M11 Protocol Template, its design principles, and intended use. The template organization and table of contents were described and reviewed along with general instructions and an explanation of terms. Finally, the key principles for design were discussed. The overall template design represents a core set of information for a clinical trial of any medicinal product(s).

Technical Specification

The third session explained the purpose and key principles of the Technical Specification, including the content and information models supporting the exchange and storage of clinical data and protocol content. The draft Technical Specification contains detailed descriptions of the components of the Protocol Template. The Technical Specification should be aligned with the latest version of the Guideline and Template, but allow for flexibility to address the data exchange needs of regional authorities. The version presented is a draft and needs input from software developers and data standard experts. This session also provided instructions on how to review the Technical Specification for public comment.

KEY THEMES FROM Q&A

General Information about the Protocol Template

The Protocol Template was designed to be applicable for interventional clinical trials across all therapeutic areas and Phases, including Phase 4.

Training materials on how to use the Protocol Template will be provided in the near future. The template is meant to provide a structure for protocols and is not intended to be training material for how to write a good protocol.

Companies that use an established template for their protocols will need to assess their templates as M11 reaches maturity and regulatory agencies determine their implementation requirements. Some realignment may need to occur.

The Protocol Template does not directly impact the development of case report forms (CRF), however, there are potentially ways the CRF could be improved.

Specific Items in the Protocol Template

The summary of each protocol amendment should briefly describe the changes to enable readers to see the evolution of the protocol through the lifecycle of the trial. Amendments should not increase the length of the protocol unnecessarily. A redline version of the protocol can be produced with the amendment summary.

Heading level one (H1) and heading level two (H2) were provided for consistency so that regardless of sponsor, type of study, staff, etc., information can be found in the same place across protocols.

Timeline and Implementation

Toward the latter half of 2023, the EWG hopes to have completed changes to the deliverables based on feedback from the public consultation period. The EWG plans to share some of the feedback at that time.

Implementation will occur at Step 5 which will likely be in 2024 and beyond.

When the template is adopted by the assembly, adoption and implementation rules will apply to all ICH regulatory members, including founding regulatory members. However, regional requirements may result in some regulatory authorities making it mandatory to adopt the template, while other authorities may recommend it.

CLOSING

A harmonized protocol template has been a goal for decades and is close to being realized. Participants in all IHC regions were encouraged to provide feedback on the Guideline through their local ICH regulatory authority or to submit questions directly to ICH during the public consultation period. The EWG appreciates the excellent input and questions submitted, and the group will take this feedback into consideration as it continues to improve the M11 Guideline and prepare for sign off, advancing more efficient clinical trials.

LIST OF SPEAKERS

Mitzi Allred, Merck & Co., Inc.

Jacqueline Corrigan-Curay, U.S. Food & Drug Administration (FDA)

Ron Fitzmartin, U.S. Food & Drug Administration (FDA)

Janice Maniwang, U.S. Food & Drug Administration (FDA)

Noémie Manent, European Medicines Agency (EMA)

ICH M11 EXPERT WORKING GROUP REPRESENTATIVES

Ron Fitzmartin, Rapporteur, FDA, United States

Noémie Manent, Regulatory Chair, EC, Europe

Claudio Nishizawa, Brazilian Health Regulatory Agency (ANVISA), Brazil

Mitzi Allred, Merck & Co., Inc.

Jayant Kumar, Central Drugs Standard Control Organisation (CDSCO), India

Simona Badoi, EC, Europe

Kerstin Koenig, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Guillaume Schoch, EFPIA

Janice Maniwang, FDA, United States

Veronica Pei, FDA, United States

Diana Koh, Health Sciences Authority (HSA), Singapore

Adam Buffone, Health Canada, Canada

Xinghe Wang, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Deven Parmar, International Generic and Biosimilar Medicines Association (IGBA)

Manabu Inoue, Japan Pharmaceutical Manufacturers Association (JPMA)

Hiroshi Tsuchiya, JPMA

Hiroshi Sakaguchi, Ministry of Health, Labour and Welfare/ Pharmaceuticals and Medical Devices Agency (MHLW/PMDA), Japan

Ken Sakushima, MHLW/PMDA, Japan

Jianzhong Zhao, National Medical Products Administration (NMPA), China

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Vivian Combs, Pharmaceutical Research and Manufacturers of America (PhRMA)

Mary Lynn Mercado, PhRMA

Antonia Valakas, PhRMA

Rawabi Felemban, Saudi Food and Drug Authority (SFDA), Saudi Arabia

Yu-Ru Lee, Taiwan Food and Drug Administration (TFDA), Chinese Taipei