A CLOSER LOOK AT THE NEW ICH E14/S7B Q&A'S AND TRAINING MATERIALS

21-22 June 2022 - 9:00 - 11:00 am EDT

Sponsored by HESI & SPS

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21 June

9:00 am EDT - 11:00 am EDT	Overview of the ICH E14/7B Q&A Training Materials and Case Studies

22 June

9:00 am EDT - 11:00 am EDT	Panel Discussion with the audience

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Training Goals

1. Recognize when nonclinical data may be used in the regulatory QT assessment, including understanding the difference between 5.1 and 6.1.
2. Recognize quality hERG and *in vivo* studies:
    a. Are the studies of reasonable quality with the appropriate quality measures?
    b. Is the study consistent with the performing lab's experience with reference agents?
3. Gain familiarity with clinical exposure definitions and how margins are defined to understand the hERG and *in vivo* margin.
4. Recognize a double-negative nonclinical package.
5. Understand what information is needed to justify the integrated QTc risk assessment.
6. Understand that there can be mitigation around some of the nonclinical study features.
7. Understand timing of various assays and how to progress to clinic.
8. Understand the flexibility of these guidelines and what alternatives may be implemented.

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21 June

9:00 am EDT **Overview of the ICH E14/7B Q&A Training Materials**
Introduction - *David Strauss, US FDA*
Integrated Risk Assessment - *Zhihua Li, US FDA*
In Vitro - Derek Leishman, Lilly
In Vivo - Hugo Vargas, Amgen
Conclusions - *David Strauss, US FDA*

10:00 am EDT **Case Studies and Scenarios for 5.1**
Moderator - Christine Garnett, US FDA
Speakers - Corina Dota, EFPIA & Wendy Wu, US FDA
Topics covered: E14 Pathways and New Options, Clinical Scenarios, Integrated Nonclinical Data (*in vitro* & *in vivo*)

10:30 am EDT **Case Studies and Scenarios for 6.1**
Moderator - Christine Garnett, US FDA
Speakers - Hugo Vargas, Amgen & Flora Musuamba Tshinanu, EMA
Topics covered: E14 Pathways and New Options, Clinical Scenarios, Integrated Nonclinical Data (*in vitro* & *in vivo*)
Summary of integrated risk data

10:50 am EDT **Q&A**
Moderator - Robert Kleiman, Clario

11:00 am EDT **Adjourn**

22 June

9:00 am EDT **Panel Discussion**
Moderators - David Strauss, US FDA & Todd Wisialowski, Pfizer, SPS President

9:05 am EDT **Introduction to the Panelists**
Corina Dota, EFPIA
Christine Garnett, US FDA
Lars Johannesen – US FDA
Derek Leishman, Lilly
Zhihua Li, US FDA
Flora Musuamba Tshinanu, EMA
Hugo Vargas, Amgen
Wendy Wu, US FDA
Takashi Yoshinaga – JPMA
Xiaodong Zhang – NMPA, China

9:20 am EDT **Q&A with the Audience**

11:00 am EDT **Adjourn**