QUESTIONS FOR THE REGULATORS

SESSION 1: Johan Luthman (Eisai, Chair)

Standardized Data: Converting Data to Actionable Insights

What is the viewpoint of the Agencies on the use of CDISC standards for regulatory submissions for drugs, and drug development tools?

- Where are FDA, EMA, PMDA in defining standards related to the use of mobile/biosensor devices in clinical trials for registration studies of drugs?
- Are there examples as precedence?

QUESTIONS FOR THE REGULATORS
(continued)

SESSION 1: Johan Luthman (Eisai, Chair)

Standardized Data: Converting Data to Actionable Insights

How do the Agencies interpret the term *Real-World Evidence* (RWE)?

- EMA, FDA, PMDA?

QUESTIONS FOR THE REGULATORS
(continued)

CAMD
Critical Path Institute

SESSION 1: Johan Luthman (Eisai, Chair)

Standardized Data: Converting Data to Actionable Insights

How do the Agencies propose the combination of data from randomized clinical trials, EHRs, and other RWE (e.g., web-based or mobile sources), that may have not been collected to a GCP standard?

- Please identify short- and long-term considerations to achieving the integration of RWE
- Are there specific examples of successful integration of RWE into the evaluation of medical products (i.e., drugs/biologics)?

QUESTIONS FOR THE REGULATORS
(continued)

CAMD
Critical Path Institute

SESSION 1: Johan Luthman (Eisai, Chair)

Standardized Data: Converting Data to Actionable Insights

What efforts are being considered by the Agencies to align incentives to ensure the generation of standardized data and sharing of RWE across the stakeholder community?

QUESTIONS FOR THE REGULATORS
(continued)

CAMD
Critical Path Institute

SESSION 1: Johan Luthman (Eisai, Chair)

Standardized Data: Converting Data to Actionable Insights

What suggestions do the Agencies have for the operational aspects of digital Drug Development Tools (dDDTs) such as:

- Standardized data collection?
- Formatting harmonization of data collected across devices, studies and sites?
- Systems to ensure production of the appropriate level of metadata and an audit trail to ensure GxP (and specifically GCP) compliance per 21 CFR part 11/EU Annex 11?
- Security around the collection of digital data and data transfers?