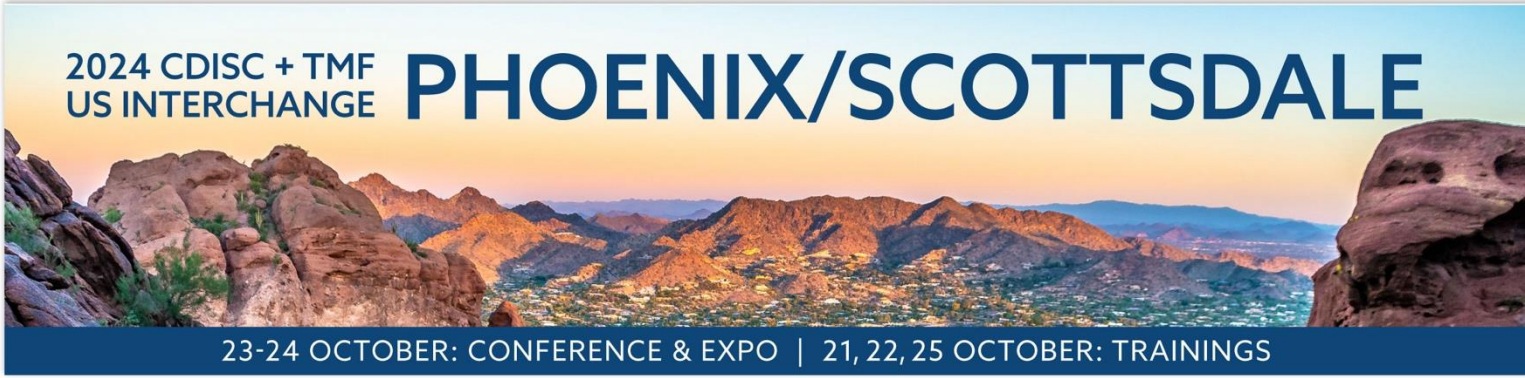


ICH Initiatives: M4Q(r2)/Q12/M11 and Global Harmonization; Impacts to Regulatory Submissions

Brooke Casselberry, Vice President Advisory and Delivery,
Epista Life Sciences

Meet the Speaker

Brooke Casselberry

Title: Vice President, Advisory and Delivery

Organization: Epista Life Sciences

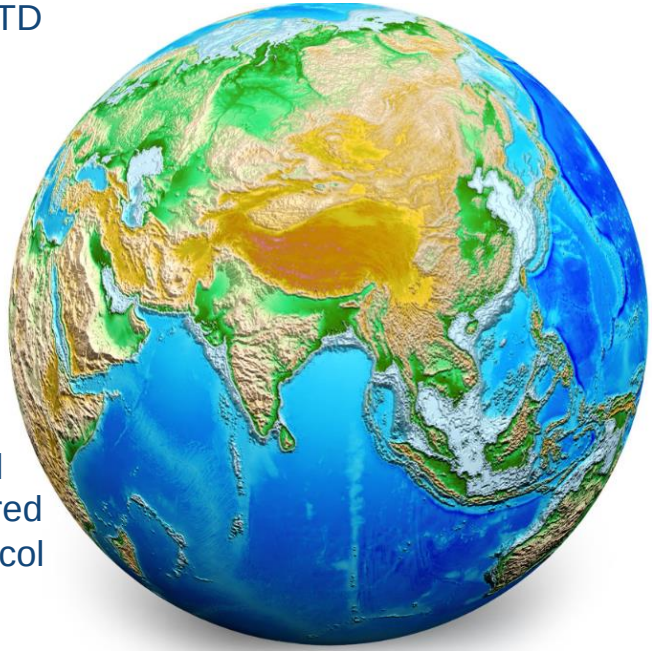
Brooke is recognized for her key collaborations with Sponsor Companies, Health Authorities, and Technology Developers. She focuses on leveraging innovative technologies to drive regulatory advancements, optimize processes, and enhance global go-to-market strategies and data harmonization. Honored as one of PharmaVoice's top 100 most inspiring individuals for her mentorship and team development, she also received the prestigious Excellence in Service award from DIA. As co-chair of the DIA RA Community, Brooke plays a vital role in shaping the conversation around data and technology in regulatory affairs.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

International Council on Harmonisation (ICH)

ICH M4Q(R2) – CTD Quality



ICH Q12 – Quality Product lifecycle management

ICH M11 – Clinical Electronic Structured Harmonised Protocol (CeSHarP)

ICH E2B(R3) – Electronic Transmission of ICSRs

IDMP - PhPID

MEMBERS

Regulatory Authorities (FDA, EMA, PMDA)

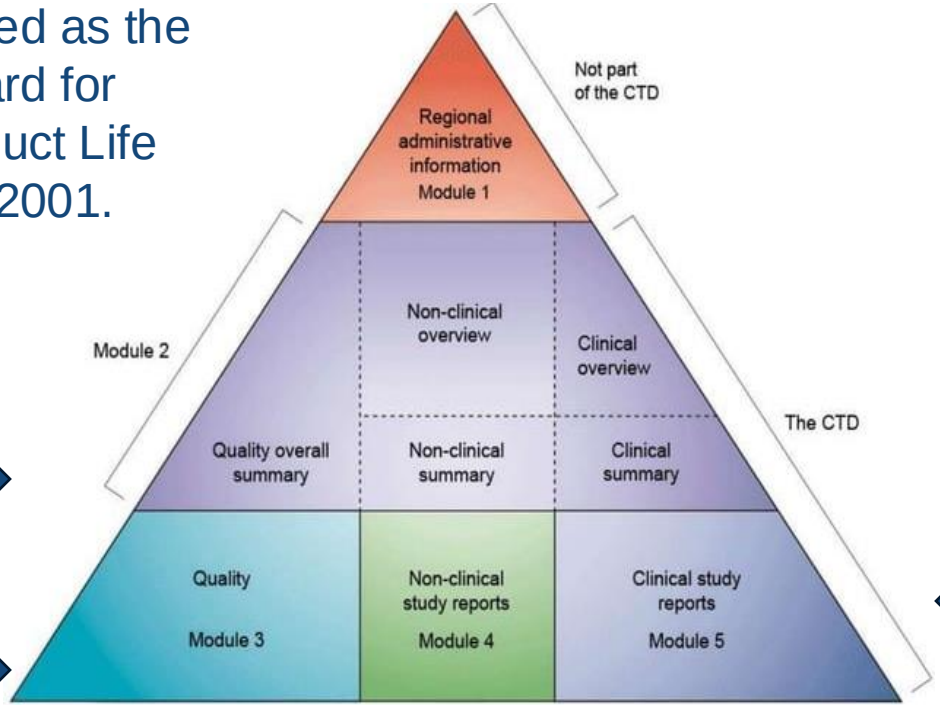
Industry Associations (PhRMA)

Observers (WHO)

cdisc

ICH M4 – Common Technical Document

eCTD – Established as the Normative Standard for Exchange of Product Life Cycle Data since 2001.



M4Q(r2) - Quality

Q12 - PAC

M11 - CeSHarP

IDMP - PhPID

ICH M4Q (r2)

- Expanded scope from M4Q(r1) to include all drug substances and products – Small Molecule/Chemical and Biologics.
- Effort to globalize standardization of the structure of Quality Information for access, analysis, and knowledge management
- Alignment to currently recognized international standards and guidelines as applicable (IDMP)
- Addressing key elements of the pharmaceutical product:
  - Quality Target Product Profile (QTPP)
  - Manufacturing process
  - Overall Control Strategy
  - Quality by Design Principals (QbD)
- Enhancements and alignment to QOS (Quality overall Summary) – M2

ICH Q12

- Effort to globalize a harmonized approach to Post-Approval Changes (PQ/CMC-PAC:PAC Reliance)
- Established Conditions (EC) parameters for post-approval changes to ensure products quality, safety, and/or efficacy is not compromised
- Quality Risk Based Development and Product Lifecycle Management From Development through Commercialization

ICH M11 – Clinical Electronic Structured Harmonized Protocol (CeSHarP)

- Harmonized Effort Across Clinical Trial Protocols
- Applicable for Global Submissions – one to many vs. many to many
- Allows for Collaborative input/review across stakeholders

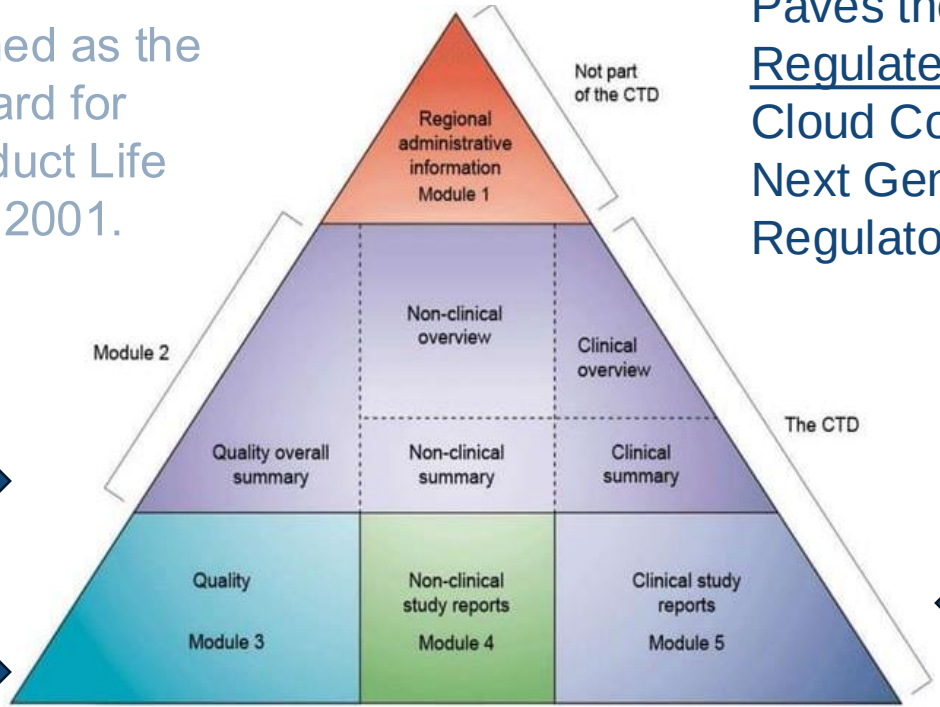
Cloud Collaboration - Opportunities

- Sponsor to Health Authority Collaboration during Product Review Cycle (e.g. Reliance Programs)
- Sponsor to Sponsor/ Sponsor to Partners/ Sponsor to CRO Collaboration during Product Development
- HQ to in-Country Affiliate Collaboration for Global Product Management (e.g. Labeling Changes)
- M&A Collaboration activities for Product Acquisitions and Divestitures
- Applicable Resourcing for Real World Evidence (RWE) accelerated submission programs

Adoption of Data Standards and Global Harmonization

eCTD – Established as the Normative Standard for Exchange of Product Life Cycle Data since 2001.

Paves the Way for Trusted Regulated Spaces (TRS) – Cloud Collaboration Next Generation of Regulatory Operations



M4Q(r2) - Quality

Q12 - PAC

M11 - CeSHarP

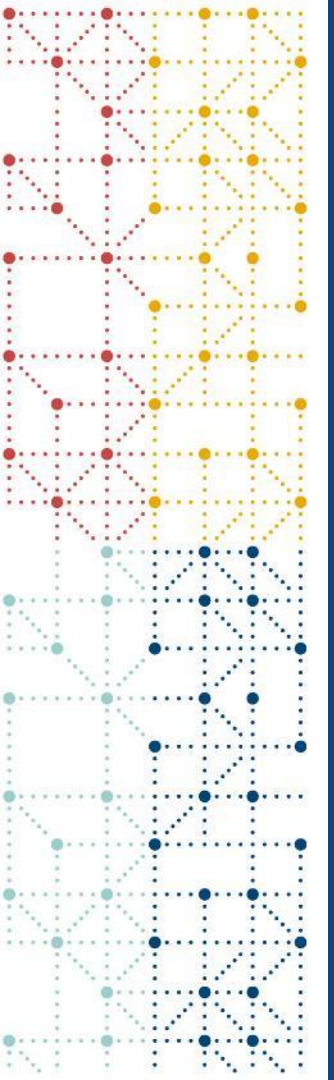
IDMP - PhPID

Benefits

- Facilitate Innovation
- Globalized Approach to Product Data Management and Regulations
- Risk-Based Approach to Product Design and Changes
- Reduced dependency on large number of resources for laborious tasks
- Increased Knowledge Management and Analytics (RWE/RWD)
- Improved Communication across Partners/Affiliates/Co-Development
- Real Time Communication across Health Authorities – Reduced Redundancy
- Better Life Cycle Management
- Reduced Time to Global Market – Reduced Cost

What can you do…..

- Participation in collaborative programs
  - Consortiums (CDISC, ISPE, PhRMA, CASSS, HL7)
- Be a Proponent for Progress
- Support Knowledge Exchange – Spread Awareness
- Data Readiness and Preparedness within your Organization
- Early Communication with Regulators
- Consideration for People, Process, Data, and how technology fits – Enterprise Ontologies



Questions

Thank You!