The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.
Current Contributions:

• Internal policy development and study data governance
• Study Data Standards Resources website
• Chair, FDA Study Data Technical Conformance Guide (sdTCG)
• Chair, FDA Business Rules
• eData mailbox responses
• eCTD Technical Rejection Criteria policy development
• TAUG evaluations for inclusion in sdTCG
• FDA Data Standards Catalog
Timeline to Required Electronic Submission Standards

**S P L R u l e**
Electronic Structured Product Labeling Rule – 2004*

**e D R L S**
Electronic Drug Establishment Registration & Drug Listing – FDA Amendment Act – 2009*

**P o s t M a r k e t S a f e t y R e p o r t R u l e**
Required electronic Individual Case Safety Reports (ICSRs) & Lot Distribution Reports, 2015*

**7 4 5 A ( a ) S t a t u t e**
Required Electronic Submission Formats under FDA Safety & Innovation Act – 2012

**7 4 5 A ( a ) G u i d a n c e**
Final Guidance on Electronic Formats under 745A(a) – eCTD, 2017*

**7 4 5 A ( a ) G u i d a n c e**
Final Guidance on Electronic Formats under 745A(a) – Study Data, 2016*

**7 4 5 A ( a ) G u i d a n c e**
Electronic Formats under 745A(a) – PQ/CMC, IND Safety Reporting

* Effective Date
Requires that submissions under section 505(b), (i), or (j) of the FD&C Act and submissions under section 351(a) or (k) of the PHS Act be submitted in electronic format specified by the Food and Drug Administration.
How the FDA communicates technical requirements for submitting study data
How the FDA communicates technical requirements for submitting study data

Binding

Non-Binding - kinda

Possible BIMO TCG
Related guidance - eCTD

Binding

Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2021
Electronic Templates
Revisions 7

Non-Binding - kinda

eCTD Technical Conformance Guide

This Document is incorporated by reference into the following Guidance Documents:

Guidance for Industry Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

For questions regarding the technical specifications, contact CDER at eCTDTechnology@fda.hhs.gov

December 2010

eCTD Data Standards 031521 (fda.gov)
Again…

Binding

Non-Binding - kinda

Possible BIMO TCG
Focus on study data

Binding

Non-Binding - kinda

Providing Regulatory Submissions In Electronic Format — Standardized Study Data
Guidance for Industry

Providing Regulatory Submissions In Electronic Format — Standardized Study Data
Guidance for Industry
Study Data Technical Conformance Guide

20 updates to sdTCG since 2014

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Provides Sponsors / Applicants with clarifications / recommendations on submission of study data

Posted to FDA webpage March and October

www.fda.gov
# Change History

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REFERENCES

https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber

• For additional information/support from CDER, please contact cder-edata@fda.hhs.gov.

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