



eGSP - Good eSubmission Practice

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Alert...!

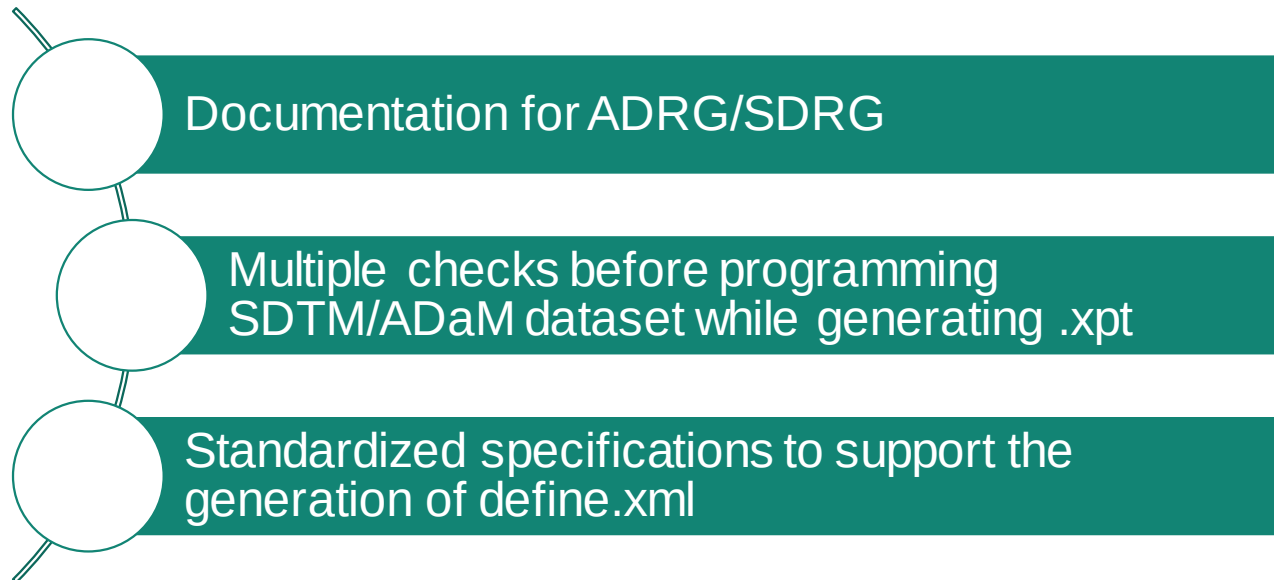
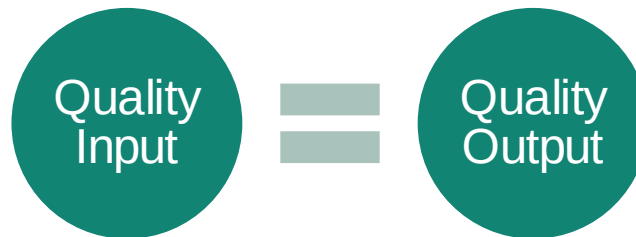
FDA Binding Guidance: A Pivotal Milestone for CDISC Standards



Final call:

Submission package must be in electronic, eCTD format.

Preparation



Quality Assurance



Data Management

- Regular communication of data issues
- Lessons Learnt should be shared for best practices
- Data Mapping and conversation



SDTM

- Automated checks for common issues
- Issue log to track issues
- Pinnacle 21 checks



ADaM

- Standard Specs templates
- Version Maintenance
- Feedback to template & data based on reviews and metrics
- Pinnacle 21 checks



eSub

- Define.xml
- ADRG/SDRG
- Dataset transport files (.xpt)
- Pinnacle 21 checks report

Pre-requirements

Electronic submissions are required for NDAs, ANDAs, BLAs, or INDs identified in that guidance be submitted in the specified electronic format.

Define.xml, Define.pdf, XPT datasets and SDRG / ADaM Data Reviewer's Guide are part of the electronic submission.

Generating define.xml for SDTM Datasets

Use the version already used or Check with Sponsor

- The latest version define.xml v2.0

Define Stylesheet (define2-0-0.xls) for define.xml v2.0

OR

define.css, define1-0-0.xls and define-extension.xsd for define.xml v1.0

Datasets

- Trimmed SDTM/ ADaM Datasets
- SAS Transport Files using Trimmed SDTM / ADaM Datasets

ADaM ADS Specifications in required format

- ADaM IG v1.0/v1.1

Documentation

- ADRG
- SAS Codes of SDTM/ ADaM Datasets
- Other documentation that is being referred in Specifications



Communication

Proper communications with submission team

- Documentation to the team working on define.xml
- Which version of define.xml to generate?
- A Stable/Final version of ADS specifications with all the derivations correctly and accurately defined
- Information to be captured in SDRG and ADRG
- A Stable/Final version of SDTM and ADaM Datasets
- Pinnacle 21 reports and justification for errors and warnings



Best Practices

- SOP's and Working Practice
 - Have strong SOPs and working practice in place to streamline process and generate high quality outputs.
- Perform random spot checks
 - Quality of ADaM code (robustness, accuracy, maintainability)
 - Feedback based on reviews
 - Checklists
 - Analyze review comments
- SMEs
 - Strong SMEs team
 - Knowledge sharing sessions
 - Discussion on new trends



Best Practices

■ Standardization

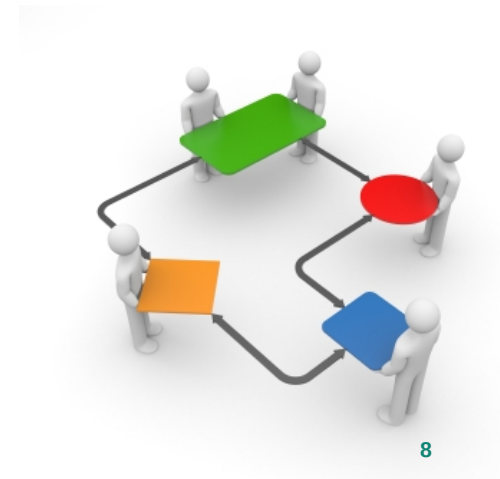
- Standardize domains according to CDISC data standard.
- CDISC data Specification for Domain.
- Specification and datasets developed from the beginning to fulfill the eSubmission requirements.

■ Quality Control and Validation Process

- Initial Pinnacle21 checks
- Expand general checklist to include the common issues based on regular assessment
- Standard Macros

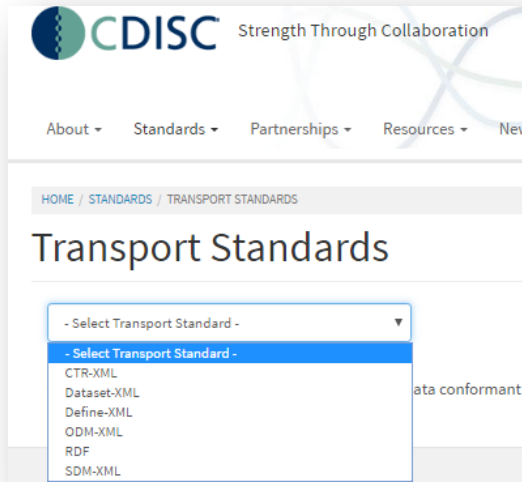
■ Efficiency

- Standard code to reduce turnaround time and effort
- Code should be capable to adapt the late stage Change
- All codes will be with proper definitions and Version control.



Code of Practice on eSubmission

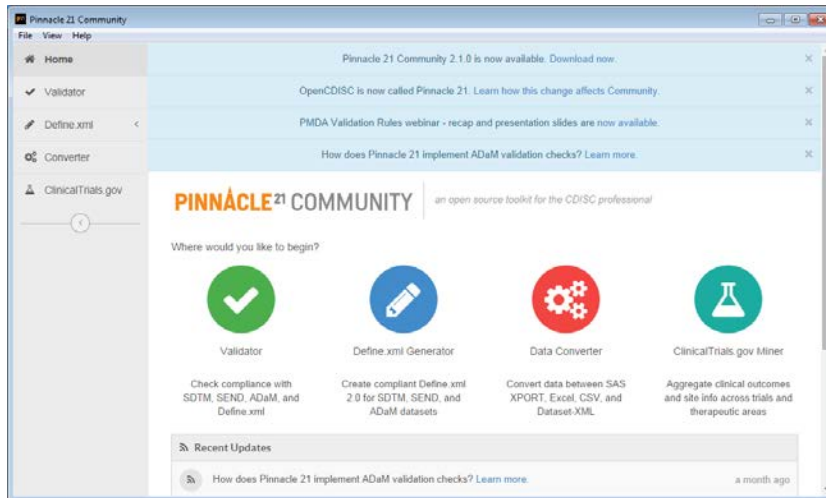
- **Responsibilities** of Programmers / Statisticians / Reviewers
- **Planning**
Proper Plan to accomplish to determine in advance what should be Regulatory \ Sponsor requirements .
- **Awareness** of eSubmission to study team
- **Training**



- **Documentation** (TMF \ Note to File \ SDRG \ ADRG)
- Proper Trackers and **tools** for review

General Information

- Pinnacle21:



- Location of Reference Material: <http://cdisc.org/define-xml>
- Location of and Guidance Document: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/default.htm>



Thank You

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