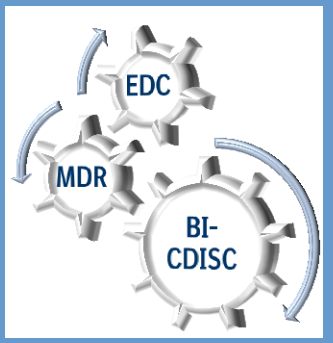
CDISC GS User Group Meeting

Submission Readiness

15 March 2016



Boehringer Ingelheim

Pinnacle21 webinar 10 Dec 2015: PMDA Validation Rules

Boehringer Ingelheim

- 77%* of all submission to FDA in 2014-15 failed to load to Clinical Trial Repository (CTR), so don't be surprise to see Reject criteria from FDA too

* Common Errors in Loading SDTM Data to the Clinical Trial Repository, Crystal Allard, FDA OCS

Recommendations

- Always use the latest available validation rules and latest version of Pinnacle 21 tools
- Comply with highest severity across agencies
  - You'll likely need to submit to both
  - Requirements will only get more strict
- Fix all issues that are fixable and explain the rest
- Follow "Continuous Compliance" approach, catch and fix data issues as early as possible

Implications

Why?

What else can be done?

Is there any experience which can be shared?

Does communication with FDA work?
- eData mailbox and beyond (SDSP…)?

Submission preparation best practices: checklist?

And what about inspections?

Practical Aspects

Points to consider:

- Define.xml: key issues, origin, link to CRF, derivation rules
- SDTM, ADaM

Controlled terminology

Validator:

- Version (which version at which timepoint?
- Handling of findings
- Various rule sets:
  - overall
  - FDA
  - PMDA
- (Rejection), Error, Warning

Transformation of source data to SDTM?

Submission failures at initial attempt