

How OpenCDISC Enterprise improved our process and compliance

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- ▶ This presentation represents the view of the author and not necessarily those of Biogen Idec, Inc.
- ▶ It is also not intended to promote the sale of any particular product but rather to characterize one implementation experience.

Agenda

- ▶ Our history with OpenCDISC
- ▶ Implementing Enterprise
- ▶ Process improvements we have experienced
- ▶ Lessons Learned so far

Biogen Idec & Statistical Data Analytics

- ▶ Significant growth in the past 5 years
 - 5 NDA/BLA submissions
 - 3 drugs approved (so far!)
 - 1 NDA projected late 2014
- ▶ Statistical Data Standards group
 - Formed in 2010
 - Currently 6 FTEs working with:
 - ~65 statistical programmers
 - ~20 drug compounds
 - ~134 clinical studies

OpenCDISC validation – background

- ▶ Data Standards Stewards are responsible for checking SDTM and ADaM compliance
- ▶ Statistical Submissions Analysts are responsible for checking define.xml compliance
- ▶ Statistical Programmers are responsible for making any necessary changes to datasets
- ▶ Our goal is NO ERRORS! and minimal post-processing

OpenCDISC validation – old process

- ▶ Whoever wanted to use the free version would download it
- ▶ Stewards were checking on a regular schedule and documenting for the Reviewer's Guide
- ▶ Difficulty moving to newer versions of the checks
- ▶ Change in company policy required IT intervention to add software to individual workstations
- ▶ Lack of consistency in documentation and communication process for getting things fixed

OpenCDISC Enterprise – benefits

- ▶ Improved communication flow
- ▶ Ability to compare results from one data transfer to the next
- ▶ Better control of decision-making about which issues to close and which to explain
- ▶ Documentation and consistency of explanations for the SDRG
- ▶ Many more validation reports to choose from
- ▶ Catalog of program and study metadata
- ▶ Latest version of the checks always available

OpenCDISC Enterprise – process (1 / 2)

- ▶ Internal Administrator to conduct training and approve system access
- ▶ Specify a single role to perform “Manager” function in OpenCDISC Enterprise
 - Set up studies
 - Assign access
- ▶ Random QA checks on consistency in study naming, title, protocol short name, phase, and type
- ▶ “Manager” and “Analyst” can load and check data, select validations to be run
- ▶ Standardized locations and naming conventions for zip files

OpenCDISC Enterprise process (2/2)

- ▶ “Manager” specifies which checks are to run for each study. Minimally:
 - SDTM v3.1.x Compliance;
 - SDTM v 3.1.x General Data Quality;
 - SDTM Controlled Terminology.
- ▶ “Whoever downloads the data checks the data”
- ▶ Interaction to resolve SDTM issues is between Data Standards Steward and the study programmer
 - DSS assigns the issue in the system to a programmer to resolve OR
 - DSS closes the issue with an explanation to be used in the reviewer’s guide
- ▶ Statistical Submissions Analyst loads define.xml and checks for compliance

Conclusion/Lessons Learned

- ▶ OpenCDISC Enterprise brings many benefits and can help bring order to the chaos of checking for CDISC compliance
- ▶ Pick a process that works for your organization, and check that it is being followed
- ▶ Work with Pinnacle21 team to identify bugs or resolve issues
- ▶ Be open to making changes

Questions?

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