ABSTRACT: The decision to accept a new drug application (NDA) or a biologics license application (BLA) for review is made on day 45 of the 21st Century Review process. JumpStart provides NDA/BLA Review Teams with data analyses early in the review process so reviewers can conduct an effective evaluation of the drug submission prior to the filing date. We summarize some common and impactful data quality issues described to reviewers. We also illustrate some customized analyses delivered in addition to standard safety explorations.

JumpStart has evaluated a total of 35 applications in FY14 and FY15. This is made up of 82 individual studies across 13 review divisions. JumpStart summarizes data quality and analyses issues in a consult, illustrates issues from the data submission, shows details of the methodology and provides an analytic output table shown below.

Examples of customized data outputs for the Division of Antivirals

### Total Applications by Division (FY14 & FY15)

- SDRG/Define/Supp Info
- Controlled Terminology
- Deaths
- Missing Data
- CDER Common Issues
- Duplicates
- Term Matching
- Standard Units
- Safety Population
- Race/Ethnicity

#### Analysis Types
- Data Quality Issues
- Data Quality Issues by Division
- Missing Data
- Duplicate Data
- Standard Units
- Safety Population
- Race/Ethnicity

#### Snapshot of Findings Discussed During Data Fitness Session

- Not including a good SDRG or Define file greatly increases the amount of time a review division must spend understanding an application. See accompanying poster for more details!
- Variables feature ambiguous values not present in the codelist which lead to confusion during review. Issue found in 60% of FY15 Applications
- Death summaries are provided to reconcile death records across an application. Typically issues stem from inconsistencies between DM, DS, AE, and CO domains. See accompanying poster for more info!
- EPOCH variable or Trial Summary domain is missing. EPOCH and Trial Summary domain are missing in 90% and 30% of FY15 Applications respectively.
- Duplicate records in the LB, VS, and EG domain with potentially contradictory information make it difficult to summarize results. Seen in 40% of FY15 applications.
- AEDECODs are missing or DSTERMs inappropriately coded to DSDECOD "OTHER". Found in 40% of FY15 applications.
- Standard Units inconsistent for a particular test making it necessary to manually convert before summarizing. Found in 30% of FY15 applications.
- Inconsistencies found between DM, EX and clinical study report. Issues are presented to the review team to ensure safety analyses are done on the proper groups. See accompanying poster for more info!
- Issues with Race or Ethnicity found in 80% of FY15 applications.

#### Other Analytic outputs

- Reconciliation between the Sponsor’s report and different methodologies
- Example of Treatment Emergent subject counts for most frequent adverse events using different methodologies

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