



TRULY EFFICIENT REVIEWS FOR CLINICAL TRIALS

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Introduction

Data from a clinical trial should be examined by as many eyes as possible. Each individual brings a unique skill set important for understanding patient safety, protocol adherence or data insufficiencies that can affect the final analysis. Clinical data review is extremely time-consuming; a major reason for this prolonged effort involves the data collection process.

To perform the final analysis as early as possible after the trial ends, data are collected and cleaned as they become available. Database software can track changes over time, but these tools are limited to few individuals and rarely available for the submission-ready data sets required for analysis. New features available in JMP Clinical 4.1 accelerate clinical trial reviews.

Methods

When clinical trial data are updated within JMP Clinical, comparisons between the current and previous snapshots identify changes at the record (row) level for each SDTM or ADaM domain. Review flags are generated to label each record as **New**, **Modified** (the contents of one or more variables has changed), **Stable** (record is identical between both snapshots), **Dropped** (record not available in current snapshot) or **Non-Unique** (comparisons cannot be performed due to duplications among the data set keys).

Subject-level review flags are generated to simplify filtering. Subjects are labeled as **Stable** (no changes or new records), **New Records** (subject has new data and possibly modifications to previous data), **Modified Records** (subject has no new data but modifications to previous data exist), or **Introduced** (subject is newly available; all data are new).

Domain keys are determined from metadata which can be easily defined by the sponsor using a PROC SORT prior to saving their data sets. Otherwise, CDISC-recommended keys are used based on the availability of the variables¹.

An extensive notes facility allows the user to create and save notes at the analysis, subject or record level. Further, system-generated notes are created to document data modifications, changes to Patient Profile review flags and dates when data is updated within JMP Clinical. Examples below utilize data from a study of Nicardipine².

Results

In the Domain Viewer Analytical Process (AP) (Figure 1), records are highlighted as **New** (yellow), **Modified** (red), **Stable** (green). Red cells indicate variables with modifications, and notes describe the nature of the change. Asterisk row markers indicate records with notes available.

Review Status Distribution AP (Figure 2) summarizes subject-level review flags and the presence of user- and system-defined notes. Data filters include record-level review flags to easily subset data to new or modified records within JMP Clinical analyses (Figure 3). A Patient Profile illustrates the **Add Note** feature and **Show New or Modified Records** button (Figure 4).

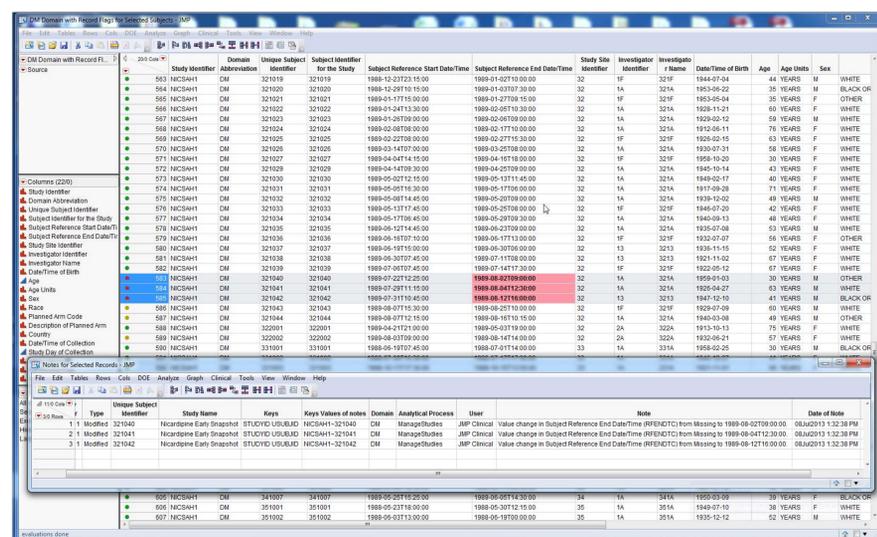


Figure 1. Domain Viewer AP displays record and variable-level changes in study data.

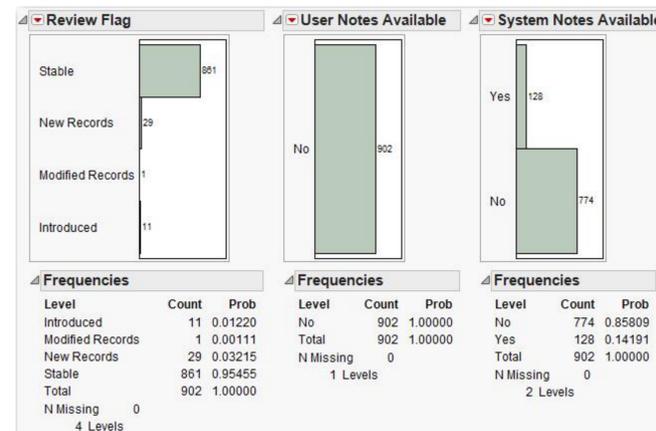


Figure 2. Review Status Distribution AP

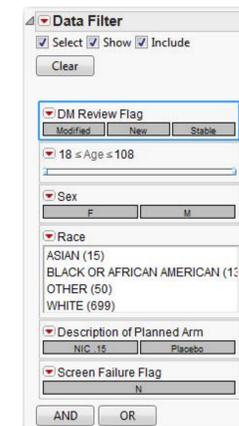


Figure 3. Data Filter with Record Review Flag

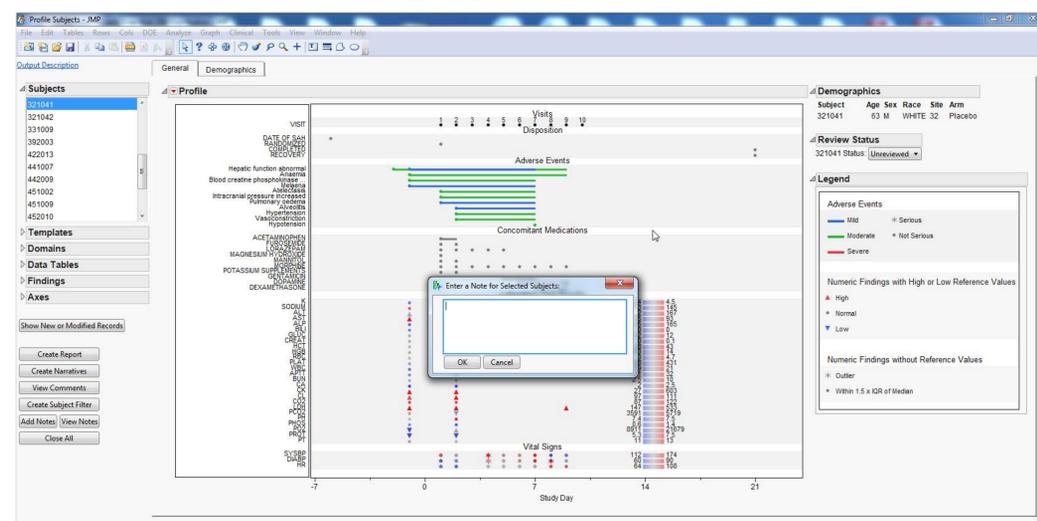


Figure 4. Patient Profile

Conclusions

These features ease the burden of data managers, clinical personnel and statisticians, and provide a way to track changes for the CDISC data sets that ultimately will be submitted to regulatory agencies. They can streamline database lock activities, allow for more efficient and accurate reviews to identify and manage potential safety concerns, and help the project team meet or exceed demanding timelines.

References

1. CDISC Submission Data Standards Team. (2008). *Study Data Tabulation Model Implementation Guide: Human Clinical Trials, Version 3.1.2*. Round Rock, TX: Clinical Data Interchange Standards Consortium.
2. Haley EC, Kassell NF & Torner JC. (1993). A randomized controlled trial of high-dose intravenous nicardipine in aneurysmal subarachnoid hemorrhage. *Journal of Neurosurgery* 78: 537-47.

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