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Automating CDISC Conformance Issue Management

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Introduction
Evaluating whether mapped data conforms to the applicable CDISC (SEND, SDTM or ADaM) standard is best done multiple times over the course of a study. This poster describes a VBA macro that facilitates the management of CDISC issues over the life-cycle of a study with support from a curated list of standardized explanations for the issue report.

Pictorial Process Overview
This process starts with the trimmed xpt files and running the CDISC review software. Once the report is generated the VBA macro can be used. The role of the VBA macro is contained within the yellow boxed portion in Figure 1. The macro facilitates migration of comments from an existing report to the newly generated report. Once the comments are migrated, the remaining undocumented issues are documented with a curated list of standard explanations. The tool also flags changes in the number of issues found. At this point, the report can be used to facilitate resolution of resolvable issues by the study team. After updates are completed and reviewed, the xpt files are recreated and the process starts again.

Curated List of Standard Explanations
A subset of the standardized explanations is on the left. The “Standardized SDRG Comment” column contains default explanatory text and accompanying notes for issues that must be resolved or cannot be resolved. The notes column provides context and helps guide review and updates. This content is used to populate the initial report; and then used on subsequent runs to populate default explanations for new issues. The “Domain(s)” column and the “Common Finding” column are used to associate the appropriate SDRG comment and notes onto a newly generated report.

VBA Macro Inputs and Outputs
Figure 3 represents a report that has already been documented. Figure 4 is a newly generated empty report. The VBA macro pulls the comments from the documented report into the newly generated report. The curated list of standard explanations in Figure 2 is used to support any missing documentation from the prior report. If there is no prior report, only the curated list is used by the macro to document the empty report.

The Final VBA Output
Here is an example of a report after the comments have been migrated from the previous report with the new issues documented with the curated list of standard explanations. Notice the comment and red cell that are circled. This red cell with a comment and the green cell with a comment are examples of how the macro provides a way to quickly compare the changes in the number of issues without manual inspection.

Conclusion
Automating CDISC conformance issue management has dramatically reduced time spent reviewing CDISC data and documenting unavoidable issues in the reviewer’s guides.

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