It is a good practice to include data definition tables (define.xml) and a reviewer’s guide along with ADaM datasets to minimize the time to familiarize with submitted clinical data and expedite the approval process by FDA reviewers. It is important to ensure consistency in metadata among data definition tables, reviewer’s guide and ADaM datasets. This paper describes automated ADaM Programming Tool, consisting of six SAS macros, to streamline the whole process from creating programming specification to generating a complete ADaM package for FDA electronic submission.

**Introduction**

**Intensive!**

**Function of Innovative ADaM Tool**

1. **Automatic consistency checking of defined terms and value level metadata between ADaM datasets & specs**
2. **Automatic generation of SAS script for final run of all ADaM specs & combination of all specs into one**
3. **Automatic track changes in analysis programming specification**
4. **Automatic define.xml generation**
5. **Automatic addition of core variables to both define.xml and ADaM datasets in final run**
6. **Automatic detection of empty variables in ADaM datasets**
7. **Automatic preparation of SAS scripts for final run of all ADaM specs & combination of all specs into one**
8. **Automatic batch file preparation for the final run of ADaM datasets**

**Decision Making On the Mismatches Between ADaM Specs and Datasets**

**Typical Report of Empty Variables**

- **Report any findings**
- **Update Programming Specifications ONLY**
- **Call a SAS macro to automatically generate a SAS program for populating core variables into ADaM Data and define.xml**
- **Ensure quality & consistency between data & specs**

**Typical Report of Tracking Changes**

- **Call a SAS macro to automatically generate a SAS program for populating core variables into ADaM Data and define.xml**
- **Ensure quality & consistency between data & specs**
- **Update Programming Specifications ONLY**
- **Less time needed, cost-effective**
- **Ensure quality & consistency between data & specs**

**Conclusion**

- **ADaM dataset structure and define.xml are all generated from the programming specification in Word, the methodology ensures the consistency & high quality of submission.**
- **The tool performs compliance checking & consistency checking of controlled terminology and value level metadata at early stage, & avoids unnecessary repetitive work at later stage.**
- **The tool can generate define.xml at any stage to facilitate statisticians to review metadata.**
- **The tool achieves the cost-effectiveness and the efficiency.**
- **The tool is easy to use and only needs minimal training.**

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