CSM Starter Program

Yusuke Morita

We implemented CSM by SAS programming with reference to CSM Reports of JMP Clinical.

Table. Correspondence between JMP Clinical report name and starter program

| JMP Clinical  report name | Function | filename | Referencing domain |
| --- | --- | --- | --- |
| Weekdays and holidays | Check if there are sites where visit dates and data collection dates are biased towards holidays | weekdays.sas | DM, SV |
| Birthday and Initials | Check if there are subjects suspected of duplicate registration | birthday.sas | DM |
| Constant Findings | Check if there are subjects whose examination values are invariant among multiple visits | constant.sas | DM, VS\*1 |
| Duplicate Records | Check for duplication of a set of measurements related to the same site or the same subject | duplicate.sas | DM, VS\*1 |
| Digit Preference | Check if there are sites with different occurrence tendency of numerical values of specific digits of inspection value | digit\_preference.sas | DM, VS\*1 |
| Multivariate Inliers and Outliers | Calculate Mahalanobis distance from multiple variables and check whether there is Inlier and Outlier | multivariate.sas | DM, VS\*1 |
| Summary Statistics | Check whether summary statistics of inspection values are different from sites at other sites | summary.sas | DM, VS\*1 |
| Finding Time Trends | Check if there are sites or subjects showing a specific tendency of the test value over time | time\_trends.sas | DM, VS\*1 |
| Perfect Scheduled Attendance | Check if there are sites where the pattern of the Visit day (VISITDY) differs from other sites | schedule.sas | DM, SV |
| (Kirkwood\*2) | Check if there are sites where any adverse event report is excessive or insufficient | ae\_rate.sas | DM, AE |

\*1：In order to facilitate understanding of the SAS program, a general VS domain was used, but it can also be applied to other Findings domain such as LB, EG, PE and ADaM (BDS) etc.

\*2：Kirkwood A, et al. Application of methods for central statistical monitoring in clinical trials. Clin Trials. 2013 Oct; 10(5):783-806.

Notes

* In the “common.sas” file, specify the storage folder of SDTM.
* Operation confirmation is done by Windows 7 + SAS 9.4TSM3.