

Improving Traceability for Complex Algorithms in ADaM Datasets

Currently, ADaM datasets implement traceability using the variable triplet SRCSEQ, SRCDOM, and SRCVAR to the maximum extent possible. These variables enable the user to identify source records from SDTM or other ADaM datasets. The usage of these variables has been largely limited to identifying a single record from the source dataset. The xxSEQ or ASEQ variable is used from the respective source dataset, as most of the ADaMs are based on a single dataset and ADSL. Traceability becomes a challenge when multiple records from a single dataset or multiple datasets contribute to the derivation of a single record in the output dataset. Common examples of such situations include, computation of cumulative dose in EX, CM; imputation of AVAL in Questionnaire data indicated by DTYPE, creation of a new parameter indicated by PARAMTYP, Oncology endpoint parameters, etc. To implement traceability for such derivations, we extended the usage of SRCSEQ by defining it as a character variable to include all the sequence numbers and their respective sources contributing to a specific record. SRCSEQ would be of the format <source>-<sequence number range> separated by '-'. For example, if two records from CM domain with CMSEQ values 29 and 40 contribute to a single record in ADCM, SRCSEQ will be set up as CM-29 CM-40. Similarly, SRCSEQ value of TR-11-13 RS-32 SE-15 SE-25 indicate that records with sequence number 11, 12 and 13 from TR domain, 32 from RS domain and 15, 25 from SE contribute to the creation of the current record. This approach provides a clear path traceable from ADaM to its source datasets irrespective of the number of source datasets contributing to its creation. We have been able to establish traceability using this approach for complex data manipulations, including, creation of new parameters, cumulative dose computations, imputation of missing questionnaire results, identifying event dates in time-to-event data etc. This paper intends to discuss this simple, yet effective, approach in detail providing implementation examples.