An ADaM-compliant ADSL dataset and its related metadata are required in a CDISC-based submission of data from a clinical study even if no other ADaM datasets are submitted. The structure of the ADSL is 1 record per subject, regardless of the type of study design. The label of the ADSL dataset is "Subject-Level Analysis Dataset." In a study, there is only 1 dataset in the class "SUBJECT LEVEL ANALYSIS DATASET," and its name is ADSL. Any other datasets with 1 record per subject would be members of other classes (e.g., the BDS, "ADAM OTHER" class).

This section lists standard ADSL variables. Within a given study, USUBJID is the key variable that links the ADSL to other datasets (both SDTM and ADaM).

For ADSL variables, the scope is "within the study." For example, the definition of SITEGR1 is consistent for all datasets within a study. It is acknowledged that the scope of USUBJID extends beyond the study, as defined in the SDTM.

There may be situations where highly derived variables are to be included in the ADSL yet the derivation of these variables may better be performed in another ADaM dataset. For example, consider the analysis need to include the baseline value of a derived parameter that is a composite score based on up to seven other parameters. These individual parameters and composite parameter may best be created in a separate analysis dataset. Different programming processes can be employed to address this analysis need, and ADaM does not dictate process.

One possible solution includes the creation of a "pre-ADSL" dataset that is used as input into subsequent analysis datasets. The final ADSL is created and collates variables as needed from any analysis dataset including the pre-ADSL dataset. If this process is employed, the pre-ADSL dataset should follow ADaM principles but may not contain all required ADSL variables.

« Analysis Results Metadata Identifier Variables for ADSL Datasets »